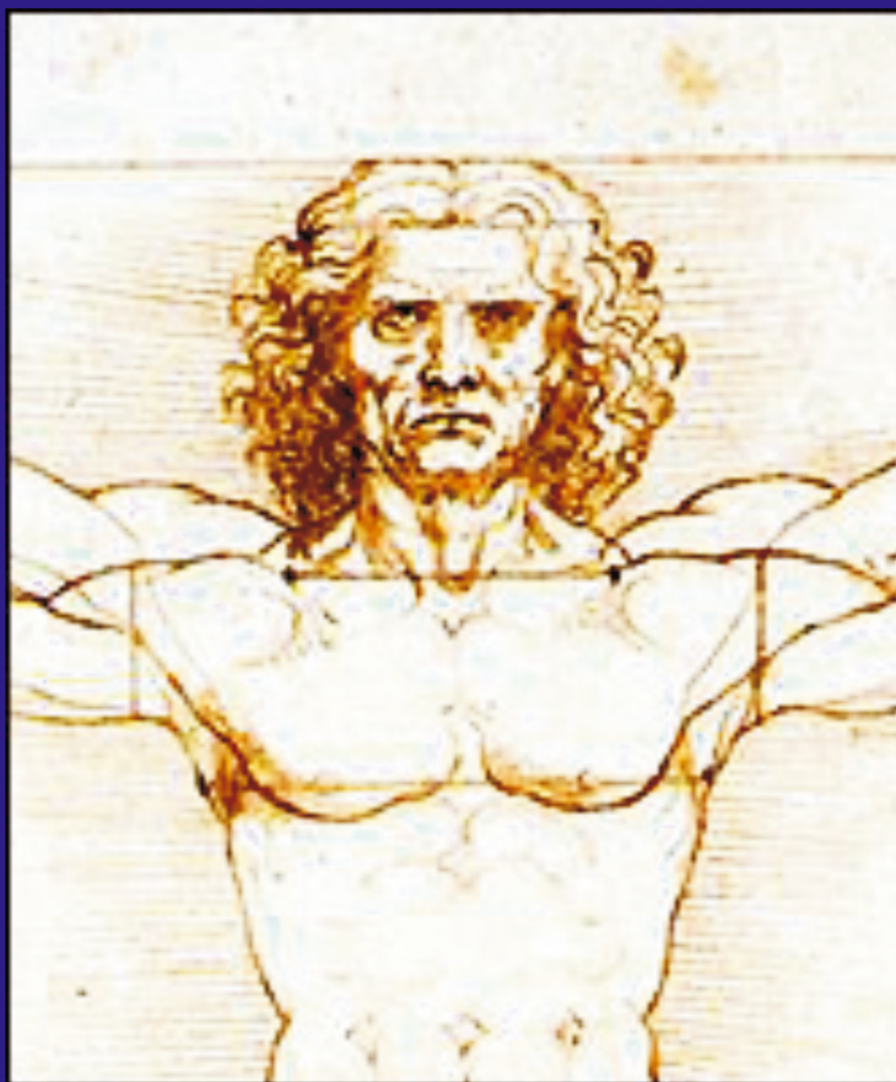


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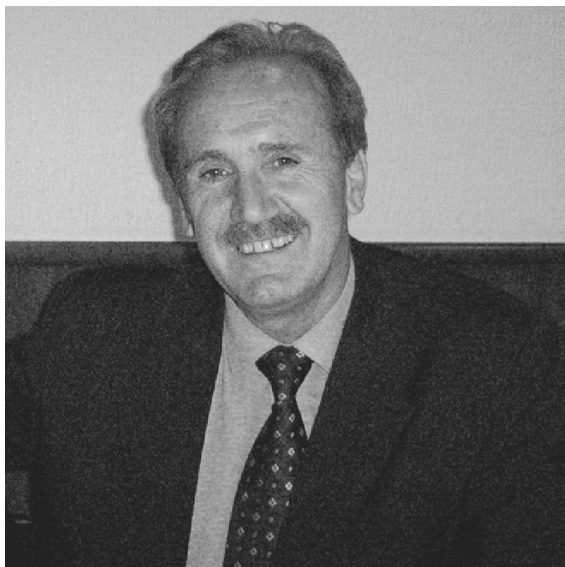
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**S poštovanjem,  
Prim. dr Avdo Čeranić  
Glavni i odgovorni urednik**

\* \* \*

*Distinguished readers,*

„Sanamed“ has waded in the second decade of its publication, and we are proud to point out that by now there has not been a single crisis, and it is constantly on a mild upward path. It has entered the library of many Universities, the number of regular subscribers, as well as citations in international journals, has also been increased. The editorial board, although under increasing obligations, does not give up in its work and with the same



amount of enthusiasm and motivation it succeeds to maintain this level of quality.

We live in a society that hardly recognizes the need for investing in science. Science is much more sought after and expected than it is invested. There are a few who appreciate the efforts of enthusiasts who voluntarily contribute to the spread of scientific thought in general. This refers to the country in which the journal is published. Nevertheless, it is similar in the countries in the region. „Sanamed“ is a small part of the mosaic of the medical world, but it is also a great legitimacy for the environment in which it has emerged. We cannot boast about a large number of journals that are of the same quality and rank as „Sanamed“. We are proud of all people who read our journal, who follow us, and most of all our associates, friends and direct activists around the globe who tirelessly work with us, because they have recognized that we are part of that family of humane people and creators. „Sanamed“ will, therefore, put efforts in continuing with the same amount of energy and it is open to anyone who wants to write and publish their news and results of their manuscripts, because it is our mutual goal.

**Yours sincerely,  
Prim dr Avdo Ceranic  
Editor in chief**

*Čitaj da shvatiš*

*Piši da preneseš*

*Uradi da te pamte*

\* \* \*

*Read to understand*

*Write to impart*

*Work to be remembered*

*Avdo Ćeranić*

## THE BURDEN OF VESICO-VAGINAL FISTULA IN ILE-IFE, SOUTH WESTERN NIGERIA

**Fehintola O. Akintunde,<sup>1</sup>** Badejoko O. Olusegun,<sup>1</sup> Ijarotimi O. Adebimpe,<sup>1</sup>  
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**Abstract: Background:** Vesicovaginal fistula is a major cause of severe morbidity and potential mortality, which can result in marital disruption, rejection, and eventual destitution.

**Methodology:** A retrospective study of all cases of vesicovaginal fistula managed over a 30 year period between 1<sup>st</sup> January 1984 and 31<sup>st</sup> December 2013 at the Obafemi Awolowo University Teaching Hospitals Complex, Ile-Ife, Osun State, Nigeria.

Relevant data were obtained from the case notes and analyzed for the demographics, clinical features, management and outcome using SPSS version 20.

**Result:** There were 213 patients with vesicovaginal fistula over the period of the study with aprevalence of 3.9 per 1000 deliveries. The age range was 15-45 years with a mean age of 24.8 years. Most of them were primiparous, (52.1%) and of the low social class (84.5%). Obstetric fistula accounted for 93.9%. The majority of them (64.8%) did not have antenatal care during the antecedent pregnancy. Labor was attended by unskilled attendants in about 90% of them while 92% labored for at least 24hours. The juxta-cervical fistula was the most common anatomical type (47.0%). The overall success rate at repair was 76.4%. Stillbirth rate in the antecedent pregnancy was 67.5%. Other associated morbidities included chronic vulva excoriation, obstetric palsy, and secondary amenorrhea.

**Conclusion:** Vesicovaginal fistula (VVF) is a major public health problem in developing countries with too many calamities as shown in this study. Improving the educational and economic status of women in Nigeria will go a long way in empowering them to access quality antenatal care. This will also enhance hospital delivery thereby preventing prolonged obstructed la-

bor which is a strong etiological factor for VVF. Decentralization of treatment centers and training of specialists in fistula surgery is very important to improving treatment outcomes.

**Key words:** Burden, Obstructed labor, Vesicovaginal fistula.

### INTRODUCTION

Vesicovaginal fistula is an abnormal communication between the epithelium of the bladder and vagina. It is a very unpleasant experience for the patients and is considered as one of the most dehumanizing conditions that affect women who often experience a lot of social problems (1).

Vesicovaginal fistula is rare in the developed world but still remains a public health problem in developing countries. This condition is much more prevalent in Northern Nigeria than the southern Nigeria where it is estimated that more than 150 000 unrepaired fistulae still exist (1).

Globally, a staggering estimate of at least 2 million women live with vesicovaginal fistula, the majority of them in the developing countries, typically represented by the VVF belt of sub-Saharan countries where Maternal Mortality Ratio (MMR) is very high. Indeed, the prevalence mirrors that of VVF in this zone (2). World Health Organization (WHO) estimated that for each maternal death, 10-15 other women sustain serious morbidity including obstetric fistula (3).

The incidence of vesicovaginal fistula tends to reflect the level of provision and usage of obstetric services in a community. These problems are particularly acute in Nigeria where at least 1% of all pregnant wo-

men will die of obstetric complications and obstructed labor (3, 4). Women who survive obstructed labor often develop vesicovaginal fistula which remains a major cause of maternal morbidity. The incidence reported in Nigeria varies between 1.4 and 3.4 per thousand deliveries and incidence of urogenital fistula following hysterectomy in England and Wales is about 1 per 1300 operations (4).

Prolonged obstructed labor remains the commonest etiological factor of vesicovaginal fistula in the developing countries while iatrogenic damage during gynecological surgeries is the commonest factor in developed countries. Other causes include traditional practices like 'Gishiri cut'; radiation therapy for genital malignancy; advanced genital malignancies like carcinoma of the cervix, vagina; obstetric procedures like forceps and vacuum deliveries, destructive operations and infection such as Lymphogranuloma venereum (LGV), Schistosomiasis (1).

Vesicovaginal fistula characteristically presents as uncontrollable leakage of urine per vaginal and the patient may, therefore, smell of urine. Other associated features in obstetric fistula include vaginal scarring, loss of tissue from the bladder or urethra and vulva excoriations from ammoniacal dermatitis (5, 6).

Amenorrhea and secondary infertility may be present. The patient may show acquired deformity of the extremities from neurological injuries to the sciatic and common peroneal nerves<sup>6</sup>. The loss of their baby and the stench of urinary and/or fecal incontinence traumatize them psychologically resulting in loss of self-esteem, they become withdrawn from the society and may be abandoned by the relatives including husband (1, 2).

Surgical closure is the definitive treatment once the diagnosis is made but the timing depends on the cause of the injury. Early closure of fistula is indicated in cases occurring at surgery, while a period of delay of about 2-3 months is advocated for cases resulting from prolonged obstructed labor and may be up to a year for radiation-induced fistula (1).

However, early closure of fresh obstetric fistulae soon after the sloughs have disappeared has been reported with good success and currently being advocated by some authors (7). Catheter treatment of fistulae is also recognized as an initial management of urinary fistula with reported spontaneous closure of small fistulae. Extensive fistulae, however, may require grafts for closure to be successful.

The success of vesicovaginal fistula repair depends largely on post-operative nursing care. With good surgical techniques and sound post-operative care, prognosis is good.

Obafemi Awolowo University Teaching Hospital Complex is located in a semi-urban part of Southwest-

ern Nigeria. The incidence of unsupervised labor is high in our environment and the attendant short and long-term complications are still seen in our practice. This retrospective study is therefore designed to determine the incidence, etiological factors, pattern of presentation and the outcome of repair of vesicovaginal fistula in our institution.

## MATERIALS AND METHODS

This was a retrospective study of all cases of vesicovaginal fistulae managed at the Ife Hospital Unit of the ObafemiAwolowo University Teaching Hospital Complex, Ile-Ife, Nigeria from 1<sup>st</sup> January 1984 to 31<sup>st</sup> December 2013.

The case notes of the patients were retrieved from the Medical Records Department and data on parity, age, anatomical type and duration of fistula, size of fistula, aetiological factor, associated morbidities and outcome of surgical treatment were extracted. The analysis was done using SPSS version 20. The results were expressed in simple percentages. Information on the educational status of the patient and the job description of the husband were used for socio – economic stratification into class 1 to 5 according to Olu-sanya et al (8). In this study, classes 1 and 2 were grouped as upper social class, class 3 as middle social class while classes 4 and 5 were grouped as lower social class to aid data analysis. Only those cases of VVF with the proper record of one form of management or the other were included in the study. Cases with incomplete or missing record were excluded. Ethical clearance was obtained from the ethics and research committee of the Obafemi Awolowo University Teaching Hospitals Complex, Ile-Ife before the commencement of the study.

## RESULTS

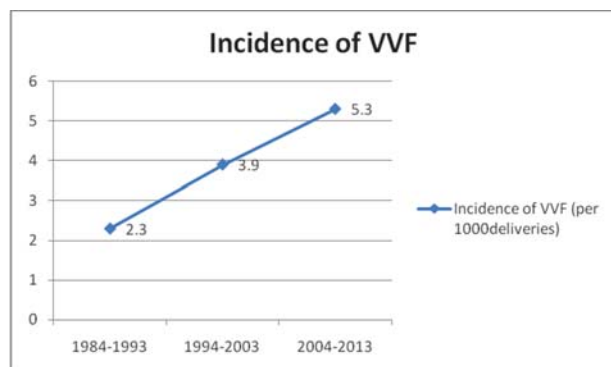
The age range was between 15 and 45 years with a mean age of 24.8 years. The peak prevalence was in the 15—24 year age group. The highest prevalence of VVF was in the primiparous patients constituting a total of 111 women (52%). About 90 women (42.2%) were Para 2—4, while 12 women (5.8%) were para5 and above. About 16 women (7.8%) belonged to the upper social class while 180 women (84.3%) belonged to the lower social class. The majority of the patients, 138 (64.8%), who had VVF didn't receive antenatal care during the antecedent pregnancy while 75 (35.3%) of them had antenatal care. Two hundred women (93.9%) had obstetric related cause while 13 women (5.9%) had non-obstetric related cause as shown in Table 1 above.

**Table 1.** Sociodemographic characteristics and etiologies of vesicovaginal fistula(VVF) in patients seen at OAUTHC Ile-Ife

| Variable                  | Frequency<br>N= 213 | Percentage |
|---------------------------|---------------------|------------|
| <b>Age group</b>          |                     |            |
| 15-24                     | 111                 | 52.1       |
| 25-34                     | 65                  | 30.5       |
| 35-44                     | 37                  | 17.4       |
| <b>Parity</b>             |                     |            |
| 1                         | 111                 | 52.1       |
| 2                         | 58                  | 27.2       |
| 3                         | 25                  | 11.7       |
| 4                         | 7                   | 3.3        |
| ≥ 5                       | 12                  | 5.7        |
| <b>Educational Status</b> |                     |            |
| No formal/Primary         | 150                 | 70.4       |
| Secondary                 | 45                  | 21.1       |
| Tertiary                  | 18                  | 8.5        |
| <b>Social Class</b>       |                     |            |
| Upper                     | 16                  | 7.5        |
| Middle                    | 17                  | 8.0        |
| Lower                     | 180                 | 84.5       |
| <b>Booking Status</b>     |                     |            |
| Booked                    | 75                  | 35.2       |
| Un-booked                 | 138                 | 64.8       |
| <b>Etiologies of VVF</b>  |                     |            |
| Obstetric related causes  | 200                 | 93.9       |
| Iatrogenic causes         | 9                   | 4.2        |
| Malignancies              | 4                   | 1.9        |

During the period of study, there were 56 154 deliveries and 213 cases of vesicovaginal fistula giving a prevalence of 3.9 per 1000 deliveries. Figure 1 below showed increase in incidence of VVF during the period under review.

Approximately 184 women (92%) out of those who developed fistula from obstetric related cause were in labor for at least 24 hours with labor duration ranging from 1-5 days and the mean duration was 2.3 days. About 180 (90%) of the patients had unsupervised

**Figure 1.** Trend of the incidence of VVF at OAUTHC Ile-Ife**Table 2.** Place of delivery, duration of labour, mode of delivery, and fetal outcome at OAUTHC Ile-Ife

| Variables                       | Frequency<br>N = 200 | Percentage |
|---------------------------------|----------------------|------------|
| <b>Place of Labour/delivery</b> |                      |            |
| At home                         | 63                   | 31.5       |
| Mission Home                    | 117                  | 58.5       |
| Private hospital                | 10                   | 5.0        |
| Government hospital             | 10                   | 5.0        |
| <b>Duration of Labour</b>       |                      |            |
| < 24 hours                      | 16                   | 8.0        |
| 24-72 hours                     | 146                  | 73.0       |
| > 72 hours                      | 38                   | 19.0       |
| <b>Mode of delivery</b>         |                      |            |
| Spontaneous vaginal delivery    | 91                   | 45.5       |
| Instrumental vaginal delivery   | 21                   | 10.5       |
| Destructive operation           | 27                   | 13.5       |
| Caesarean section               | 47                   | 23.5       |
| Caesarean hysterectomy          | 14                   | 7.0        |
| <b>Fetal outcome</b>            |                      |            |
| Alive                           | 65                   | 32.5       |
| Dead                            | 135                  | 67.5       |

**Table 3.** Anatomical type and size of fistula in patients with obstetric vesico-vaginal fistula at OAUTHC Ile-Ife

| Variable               | Frequency<br>N = 200 | Percentage |
|------------------------|----------------------|------------|
| <b>Anatomical type</b> |                      |            |
| Juxta- cervical        | 94                   | 47.0       |
| Juxta-urethral         | 67                   | 33.5       |
| Mid-vagina             | 39                   | 19.5       |
| <b>Size of fistula</b> |                      |            |
| < 2 cm                 | 120                  | 60.0       |
| 2-3 cm                 | 54                   | 27.0       |
| 4-5 cm                 | 18                   | 9.0        |
| ≥ 6 cm                 | 8                    | 4.0        |

sed labor at home and the mission houses while only 20 (10%) women labored in health care facility as shown above. Of the 200 patients with obstetric cause, 109 (54.5%) of them had some forms of operative delivery as shown below while the remaining (45.5%) had spontaneous vaginal delivery. Prolonged labor contributed to poor perinatal outcome in these patients with stillbirths recorded in 135 (67.5%) of the antecedent deliveries and live births in 65 (32.5%) of patients.

Majority of the fistula are juxta-cervical fistula which accounted for 47.1 % of cases. About 15 (7.5%) of women with VVF had a concurrent rectovaginal fistula. The size of the fistula ranged between 2 cm — 6 cm. About 120 (60%) of the women had fistula less than 2 cm while only 8 (3.9%) of them suffered extensive fistula.

## MANAGEMENT OUTCOME

Out of the 200 women with obstetric VVF, 180 (90.0%) had VVF repair while 8 (4.0%) were lost to follow-up before surgery. Twelve patients (6.0%) had spontaneous closure with complete resolution of symptoms during prolonged catheterization. Transvaginal route of repair accounted for majority of the repair in 157 (87.2%) of patients, while the transabdominal route was used in 23 (12.8%) of patients. About 128 (71.1%) of the 180 women had successful VVF repair at first attempt while additional 10 (5.3%) achieved continence at second attempt with overall success rate of 76.4%.

## ADDITIONAL MORBIDITIES

There were other associated morbidities found in these patients. About 37.3% of them had chronic excoriation of the perineal skin due to ammoniacal dermatitis; obstetric palsy (foot drop) was observed in 37 (18.3%) while 11.8% of the women had secondary amenorrhoea.

## DISCUSSION

One of the most devastating consequences of obstructed labor is the vesicovagina fistula (1, 2). Approximately 94% of fistula in this series was due to obstetric causes. This was similar to findings of Ijaiya et al where 84.1% of fistulae reported in their series were due to obstetric causes (4).

In the developing world, the true incidence of vesicovagina fistula is unknown, as many patients with this condition suffer in silence and isolation. Some estimates place the prevalence as high as 2 million women worldwide (6).

The prevalence of VVF of 3.9 per 1,000 deliveries in this study was similar to the estimated prevalence range of 3 – 4 per 1,000 deliveries reported for West Africa (7) and 3.5 per 1,000 deliveries reported by Harrison in Kaduna (2). It is, however, higher than 1.4 per 1,000 deliveries reported from Ilorin (4).

This relatively high incidence from a southern hospital may be due to the fact that our Hospital is a referral center for about four states.

During normal labor, the bladder is displaced upwards in the abdomen so the anterior vaginal wall, bladder base, and urethra are compressed between the fetal head and the posterior part of the pubic bone. If this occurs for a short period of time, there is no tissue damage. If, however, there is prolonged obstructed labor, the intervening soft tissue becomes ischemic. The area undergoes pressure necrosis and within 3-10 days post partum, the tissue sloughs off.

Typically, the length of pressure without relief is more important than the magnitude of pressure. About 92% of women in this study were in labor for at least 24 hrs, with some labor lasting as long as 6 days. This result is similar to the series in fistula hospital in Addis Ababa where the average length of labor was 3.9 days (9).

The typical fistula patient is young, primiparous, separated from her partner and had little or no education. This is similar to findings in this study in which the mean age of majority of the patient was 24.8 years, 79.3% of the women were of low parity (para 1 and 2) and 84.5% belonging to lower social class (class IV and V).

This result is also similar to earlier studies (4, 10). The high prevalence in the young primiparous women may be due to the occurrence of cephalopelvic disproportion because the pelvis is not fully developed to allow for normal vaginal delivery (11, 12).

Furthermore, many of these patients have unsupervised labor with a resultant high incidence of prolonged obstructed labor and subsequent fistula formation. Because of the low level of literacy in these women, they maintain subordinate position in the society and are excluded from decision-making, even decision about their own health.

These and other contributing factors cause late presentation for treatment. The average duration of fistula before presentation for care in this study was 6.2 yrs. This is similar to mean duration reported by Sunday-Adeoye (13).

The pattern of prevalence of vesicovaginal fistula over the 30 years under review showed gradual increase with more and more patients presenting to our center for treatment. This mirrors the increased incidence of obstructed labor with its attendance complications. The reason for this increase as seen in some other African countries like Ethiopia is that the contributing factors still persist and even getting worse (14).

Many women in developing countries have contracted pelvis, most often as a result of malnutrition and increased infection rate in adolescent leading to growth stunting and poor development. This is compounded by early marriage and childbearing and female genital mutilation (12, 13, 14).

Many women rely on traditional healers and mission houses because they are viewed as more accessible and familiar. They view hospital as the place to die and not a place for delivery. Physical barriers that prevent hospital delivery include; limited transportation and poor road network (15).

Juxta-cervical fistula was the commonest type of fistulae in this study. This is similar to the findings in other studies (13, 16, 17). This is probably due to the fact that obstruction in labor at the pelvic brim is commoner in this part of the world.

The majority of the patients in this study presented with total urinary incontinence. About 14.7% of the patient presented with combined fistula (VVF and rectovaginal fistula).

Vaginal examination in the clinic was difficult in 98% of the patient because of vagina scarring with varying degree of dermatitis, gynaetresia and vulva excoriation necessitating Examination under anesthesia before accurate diagnosis could be made.

There are two routes to VVF repair - abdominal and vaginal routes. Some of the procedures that can be done through vaginal route include saucerization, flap sliding, Simple lay open etc. depending on the types of fistula. Contraindications to vaginal approach include: severely indurated vaginal epithelium around the fistula, small capacity or poorly compliant bladder, repair requiring ureteral reimplantation, involvement of other pelvic structures, vaginal stenosis, or inability to obtain proper exposure (18). The abdominal approach has been recommended for: high retracted fistulas in a narrow vagina; fistulas which are proximal to the ureters; cases with associated pelvic pathology, and multiple fistulas (18). Very high or large VVFs either in close proximity to ureteric orifices or when associated with hydronephrosis, hydroureter, or urinary ascites or absent vaginal cuff are considered to be complex fistulas and require a transabdominal transvesical approach. The successful management of such fistulas is largely dependent on judicious use of interposition flaps. The omental flap is undoubtedly the most versatile; it can be used in abdominal and combined abdominal-vaginal procedures. Surgery needs to be performed in a center of excellence and questions regarding adequacy of surgical experience, technical expertise, nursing care, and facilities for blood transfusion need to be addressed before attempting complex vesicovaginal repairs.

Moreover, the laparoscopic repair of vesicovaginal fistula without opening the bladder and using intracorporeal suturing and omentum interpositioning is a feasible procedure in selected patients. It will be a useful adjunct to transvaginal repair of fistulas if the surgical morbidity of the open abdominal approach is decreased. Laparoscopic VVF repair is most useful in the same scenarios as the transabdominal repair, such as in the setting of a high VVF in which a vaginal operation would be anatomically challenging. Although the laparoscopic approach in expert hands may provide high success rate, it is not widely practiced due to the costs and considerable learning curves imposed by intracorporeal laparoscopic suturing, a requirement for VVF repair, which is an advanced skill many surgeons lack (19, 20). Successful robotic VVF repair was first reported in 2005 (21). A five-port technique has been descri-

bed using a vaginal pack to maintain pneumoperitoneum throughout the case (21).

In this study, approximately 85% of the VVF were not larger than 3 cm in diameter and were repaired transvaginally using either Saucerization or simple lay open technique. The combined fistulae repaired during the period under review were by the traditional three stage procedure. There were 12 cases of closure with flaps. There was no early closure in this study as advocated by some authors especially following hysterectomy (22).

Combined VVF and RVF used to be a three-stage procedure in which VVF repair is followed by diversionary colostomy and finally RVF repair (3 weeks later). Now combined VVF and RVF repair can be done at once with no need for diversion colostomy and 67 % success rate in a study (23).

The overall success rate of 76.4% recorded in this series is in agreement with rates of 85% and 87.9% reported from other studies in Nigeria (2, 4). All the repairs were mainly through the vagina approach or occasionally abdominal.

Mode of delivery in subsequent pregnancy following successful repair could not be ascertained because there were no records of these in majority of the patients' case notes. However, 25 (18.2%) of the patients with successful repair were delivered by Caesarean Section in their subsequent pregnancies.

The limitation of this study was the lack of follow-up and poor documentation of information. Data was scanty and poorly documented. Other limitations of this study were the fact that it was an institution-based study with the limited power on account of the small sample size. These limitations must be borne in mind when making extrapolations to the general population.

## CONCLUSION

Vesicovaginal fistula (VVF) is a problem of under-development with too many calamities as shown in this study; as such the best solution will be by putting in place appropriate integrated development programs that are community-based and sustainable. Such approach should be one that will strengthen the local capacity available to women to improve their health and social environment through the implementation of co-ordinated model programs. Such programs should include those that address the social and economic status of the community as a whole with focus on girl-child education, adult literacy programs and income generating skills development for women of childbearing age. Also necessary are, appropriate, affordable and accessible health services provision at the grassroots

level. This will enhance hospital delivery thereby preventing prolonged obstructed labor which is a strong etiological factor for VVF. Training of specialists in fistula surgery is very important to improving treatment outcomes.

### Competing interests

The authors declare that they have no competing interests.

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### Disclosure statement:

None of all authors

### Licensing

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### Abbreviations

**VVF** — Vesicovaginal fistula  
**MMR** — Maternal Mortality Ratio  
**WHO** — World Health Organization  
**LGV** — Lymphogranuloma venerum

### Sažetak

## UČESTALOST VEZICO-VAGINALNIH FISTULA U ILE-IFE-u, U JUGO-ZAPADNOJ NIGERIJU

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**Uvod:** Vezikovaginalna fistula je jedan od vodećih uzroka ozbiljnog morbiditeta i potencijalnog mortaliteta kod žena, koji se može reflektovati i na bračne probleme, socijalno marginalizovanje, odbijanje i eventualno u destituciji.

**Metodologija:** Retrospektivna studija svih slučajeva vezikovaginalnih fistula prikupljenih u proteklih 30 godina između 01. 01. 1984. i 31. 12. 2013. u Obafemi Awolowo Univerzitetskoj bolnici, Ile-Ife, država Osun, Nigerija. Relevantni podaci, prikupljeni iz istorija bolesti, analizirani su prema demografskim i kliničkim karakteristikama, pristupu u lečenju i ishodu, koristeći SPSS verziju 2.0.

**Rezultati:** 213 pacijenata sa vezikovaginalnom fistulom je obuhvaćeno studijom u navedenom period praćenja, sa prevalencom od 3,9 na 1000 pacijenata. Starost pacijenata se kretala između 15-45 godina sa srednjom vrednošću od 24,8 godina. Većina pacijentkinja su bile prvorotke (52,1%) i pripadnice niže socijalne klase (84,5%). Obstetrična fistula se pojavila u 93,9%. Većina (64,8%) nije imala odgovarajuću ante-

natalnu negu tokom trudnoće. Porođaj je vođen od strane nestručnog osoblja u oko 90% slučajeva, i kod 92% porođaj je trajao minimum 24h. Jukstacervikalna fistula je bila najčešći anatomski tip (47%). Sveukupni uspeh korekcije je bio oko 76,4%. Stopa mrtvorodenčadi je bila 67,5%. Ostali morbiditeti su uključivali hronične ekskoriacije vulve, akušersku paralizu i sekundarnu amenoreju.

**Zaključak:** Vezikovaginalna fistula je veliki problem javnog zdravlja u zemljama u razvoju sa mnogo nesrećnih slučajeva, kao što je prikazano u ovoj studiji. Poboljšanje obrazovnog i ekonomskog položaja žena u Nigeriji će im omogućiti pristup kvalitetnijoj antenatalnoj nezi. Ovo će takođe povećati i broj porođaja vođenih u bolnici, što će biti prevencija produženog porođaja, koji je najznačajniji etiološki faktor u pojavi VVF. Decentralizacija ustanova, kao i edukacija specijalista u hirurgiji fistula je od esencijalnog značaja za unapređenje kvaliteta operacija i poboljšavanje ishoda.

**Ključne reči:** teret. produžen porođaj, vezikovaginalna fistula.

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## RELATIONSHIP BETWEEN PHYSICAL ACTIVITY AND HEALTH-RELATED QUALITY OF LIFE IN ELDERLY PEOPLE: A CROSS-SECTION STUDY

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**Abstract: Objectives:** This study aimed to investigate the relationship between physical activity level and health related quality of life in elderly people.

**Design:** Between January and April 2017, a cross-sectional study of 114 elderly people (73 males and 41 females) conducted this study. Their mean age was ( $71 \pm 5.24$ ) and the mean body mass index (BMI) was ( $29 \pm 3.31$ ). The participating elderly were classified according to walking duration into two groups, low level of physical activity (walking duration  $<150$  min/week) and high level of physical activity (walking duration  $> 300$  min/week). The health-related quality of life (HRQoL) was measured using the Euro Qol-5 dimensions-3 levels scale questionnaire (EQ-5D-3L). Statistical analysis was used to determine the relation between the physical activity and HRQoL scores in elderly people.

**Results:** The measures showed statistically significant differences between high and low physical activity groups ( $p < 0.05$ ). The group of high physical activity showed higher HRQoL scores more than the group of low physical activity in the all five dimensions. The low level group showed high predominance of the chronic disease.

**Conclusions:** High level of physical activity has a beneficial effect on all dimensions of the HRQoL in elderly people. Effort and awareness should be dedicated to encouraging the active lifestyle among different population especially elderly people.

**Keywords:** elderly, physical activity, HRQoL, EuroQol.

### INTRODUCTION

Aging is rapidly increasing worldwide (1), health governments are highly interested in protecting and

advancing the level of health with live ignited and sustaining the maximum life quality. Kindred population above 65 years old has heightened significantly in Spain, between 1975 and 2015 from 10-18% of the total number of people (2).

HRQoL is a health condition symptom of the people's everywhere and it can be a necessity for distinct contexts, as experimental researches, assessments of health care stinting or health of population reconnoiter (3). Many various approaches of HRQL live, the HRQoL was defined as the measure appointed for the life period, which adjusted with the deteriorations, conditions of function, intuitions and possibility socially that are affected through illness, injuries, handling or treatment and guidelines (4). Many templates directing to these various dimensionally thought were suggested throughout these years (5, 6).

The HRQoL model comprises of many domains, including overall quality of life (QoL), general health, symptom, biological, and functional statuses, not only the mentioned five domains but also include environmental and individual dimensions. Every domain affects directly on the subsequent domain (function status is affected by symptom status and this affected by biological variables). But the environmental and individual variables influence directly all domains measure except biological domain (5).

The HRQoL is one of many dimensions conceptualization that view social, mental, and physical outlooks (7). The HRQoL evaluation is a critical constituent of physical and mental health assessment (8). Several implements were matured to evaluate HRQoL in various communities. Many important factors are associated with clinical and demographic characteristics, compri-

sing patient age, medical status, language, and culture of the community are vital information to use a related reliable and valid measure of HRQoL (8, 9).

Physical activity seems to be related to improving functional performance and HRQoL (7, 9, 10, 11). Physical exercise may assist older adults repurchase or sustain a the health of aging people (12). Regular leisure time of physical exercise can lead to high level of HRQoL in elderly people (13, 14).

Also, regular physical activity may proportionately assist elderly people to inhibit a decrease of HRQoL and enhance the enjoyment of their life (15). Because of these important determinants that support better elderly health, evaluating the relationship between physical activity level and HRQoL scores in elderly people became greater needed, particularly compared to the increase of the elderly number in the world. This study aimed to evaluate the relationship between physical activity and HRQoL scores in elderly people.

## SUBJECTS AND METHOD

Between January and April 2017, a cross sectional study on 114 elderly people (73 males, 41 females) aged  $\geq 65$  years were recruited in this study. All participants were considered eligible when they met the inclusion criteria of being independent walking without any cognitive disorders. This independent walking was evaluated according to walking capacity of the participants (can walk at least 6 minutes without assistance) (10). All subjects with severe life limiting illness, orthopaedic limitations, cognitive disorders that couldn't know anything about his age, childhood, and couldn't respond to examiner questions were excluded from this study. The participating elderly were classified according to walking duration into two groups, low level of physical activity (walking duration  $<150$  min/week) and high level of physical activity (walking duration  $>300$  min/week) (10). Each participant was informed about the objectives and procedure of the study and instructed to sign a written informed consent before starting the study. It was conducted at the outpatient physical therapy department, College of Applied Medical Sciences, Prince Sattam Bin Abdul Aziz University.

### Procedure

Assessment procedures which were done through using the following:

a- Baseline clinical characteristics questionnaire; the patient data were recorded, including; age, gender, height, weight, work, past medical disease, medications, habits, motor or sensory dysfunctions.

b- The HRQoL questionnaire: It was measured using an Arabic version of the Euro QoL-5 dimensions-3

levels scale (EQ-5D-3L). It is a standardized instrument for measuring outcomes of health. It is well validated, reliable, and not need more time or effort to be completed and has been documented in many previous studies to measure HRQoL in a wide range of health conditions (16-18). It includes descriptive system (5 dimensions) and EQ visual analogue scale (EQ-VAS).

The EuroQoL group approved the validated Arabic version of the EQ-5D questionnaire to assess elderly people QoL (19). The EQ-5D comprises 5 dimensions, including; mobility, self care, usual activities, pain/discomfort, anxiety/depression. Each domain-consists of 3 levels (no problems, slight/moderate problems, and severe/extreme problems). EQ-VAS assess HRQoL with 0-100 endpoints, 0 is the lowest imagine health and 100 is the highest imagine health.

### Data Analysis

Descriptive statistics was done in the form of mean and standard deviation to assess the sample based on the physical activity and HRQoL. Mann-Whitney test was used to assess the arranged measures of EQ-5D. The Spearman's correlation coefficient was used to measure the strength and direction of the relationship between the physical activity and HRQoL. All analysis was done using SPSS version 18.0 (SPSS, Chicago, IL) with statistical significance at p-value  $\leq 0.05$ .

## RESULTS

114 elderly people (73 males and 41 females) participated in this study. Their mean age was  $(71 \pm 5.24)$  and the mean body mass index (BMI) was  $(29 \pm 3.31)$ . 70.2% of the participants were diagnosed clinically with chronic disease as the following; 25.4% diabetes mellitus, 31.6% hypertension, 13.2% cardiovascular disease. About 93% the participating elderly weren't smoking and only 7% were smoking. Sleep quality was good in 83% of subjects and bad in 17% of subjects. Walking duration was less than 30 min/day in seventy six subjects and more than 30 min/day in thirty eight subjects. Clinical characteristics of all participating elderly demonstrated in Table 1. Also, clinical characteristics in high and low level of physical activity are demonstrated in Table 2.

The outcomes of HRQoL measures exhibited that the group of low physical activity level suffered walking problems started from slight/moderate to severe/extreme level as (90.3%, 64.5%, 85.5%, 88.2%, 81.6%) of the participants in mobility, self-care, usual activities, pain/discomfort, and anxiety/depression dimensions respectively. While the group of high physical activity level suffered waking problems only in slight/moderate

**Table 1.** Clinical characteristics of the all participants

| Characteristics                          | N (%)                 |
|------------------------------------------|-----------------------|
| Sex                                      |                       |
| Males n (%)                              | 73 (64)               |
| Females n (%)                            | 41 (36)               |
| Age mean $\pm$ SD                        | 71 $\pm$ 5.24         |
| Height (cm) mean $\pm$ SD                | 161 $\pm$ 3.4         |
| Weight (kg) mean $\pm$ SD                | 76 $\pm$ 7.14         |
| BMI (kg/m <sup>2</sup> ) mean $\pm$ SD   | 29 $\pm$ 3.31         |
| <b>Medical diagnosed chronic disease</b> |                       |
| Yes/No n (%)                             | 80 (70.2) / 24 (29.8) |
| Diabetes Mellitus                        | 29 (25.4)             |
| Hypertension                             | 36 (31.6)             |
| Cardiovascular                           | 15 (13.2)             |
| Smoking habits (yes/no)                  | 8 (7) /106 (93%)      |
| Sleep quality (good/bad)                 | 95/19                 |
| <b>Walking duration n (%)</b>            |                       |
| Less than 150 min/week                   | 76 (66.6)             |
| More than 300 min/week                   | 38 (33.4)             |

level as (36.8%, 23.7%, 31.6%, 60.5%, 52.6%) of the participants in the five dimensions respectively. No participant suffered any walking problems in severe/extreme level in all dimensions in a high physical activity group. The results showed statistically significant differences between the two groups; high and low physical activity groups ( $p < 0.05$ ). The group of high physical activity exhibited higher measures more than the group of low physical activity in the all five dimensions. On EQ-VAS measure, the high level group showed higher scores more than a low level group ( $p < 0.05$ ) as demonstrated in Table 3.

With correlation coefficient statistical analysis, strong positive correlation was exhibited in this study between physical activity level and the all five dimensions of the EuroQol questionnaire. This strong positive correlation means that higher physical activity level goes with high HRQoL scores (and vice versa) as demonstrated in Table 4.

**Table 2.** Clinical characteristics in the two groups; low and high level of physical activity

| Items                        | Low physical activity<br>(n = 76) | High physical activity<br>(n = 38) | p-value |
|------------------------------|-----------------------------------|------------------------------------|---------|
| Sex (male/female)            | 49/27                             | 24/14                              | < 0.05  |
| BMI (kg/m <sup>2</sup> )     | 31.2 $\pm$ 3.5                    | 29.3 $\pm$ 4.2                     | < 0.05  |
| Chronic disease n (%)        | 71 (93.4)                         | 9 (23.7)                           | < 0.05  |
| Diabetes mellitus n (%)      | 27 (35.5)                         | 2 (5.3)                            | < 0.05  |
| Hypertension n (%)           | 32 (42.1)                         | 4 (10.5)                           | < 0.05  |
| Cardiovascular disease n (%) | 12 (15.8)                         | 3 (7.9)                            | < 0.05  |

**Table 3.** HRQoL measures in low and high physical activity levels

| HRQoL items              | Low physical activity<br>(n = 76) | High physical activity<br>(n = 38) | p-value |
|--------------------------|-----------------------------------|------------------------------------|---------|
| Mobility n (%)           |                                   |                                    |         |
| No problems              | 7 (9.2)                           | 24 (63.2)                          | < 0.05  |
| Slight/Moderate problems | 58 (76.3)                         | 14 (36.8)                          | < 0.05  |
| Severe/Extreme problems  | 11 (14.5)                         | 0                                  | < 0.05  |
| Self-care n (%)          |                                   |                                    |         |
| No problems              | 27 (35.5)                         | 29 (76.3)                          | < 0.05  |
| Slight/Moderate problems | 43 (56.6)                         | 9 (23.7)                           | < 0.05  |
| Severe/Extreme problems  | 6 (7.9)                           | 0                                  | < 0.05  |
| Usual activities         |                                   |                                    |         |
| No problems              | 11 (14.5)                         | 26 (68.4)                          | < 0.05  |
| Slight/Moderate problems | 51 (67.1)                         | 12 (31.6)                          | < 0.05  |
| Severe/Extreme problems  | 14 (18.4)                         | 0                                  | < 0.05  |
| Pain/discomfort n (%)    |                                   |                                    |         |
| No problems              | 9 (11.8)                          | 15 (39.5)                          | < 0.05  |
| Slight/Moderate problems | 52 (68.4)                         | 23 (60.5)                          | < 0.05  |
| Severe/Extreme problems  | 15 (19.8)                         | 0                                  | < 0.05  |
| Anxiety/depression n (%) |                                   |                                    |         |
| No problems              | 14 (18.4)                         | 18 (47.4)                          | < 0.05  |
| Slight/Moderate problems | 43 (56.6)                         | 20 (52.6)                          | < 0.05  |
| Severe/Extreme problems  | 19 (25)                           | 0                                  | < 0.05  |
| EQ-VAS (Mean $\pm$ SD)   | 60 $\pm$ 11.42                    | 87 $\pm$ 8.31                      | < 0.05  |

**Table 4.** The Spearman' correlation coefficient between HRQoL and Physical activity levels

| HRQoL items               | 95% confidence interval |        | $r_s$  |
|---------------------------|-------------------------|--------|--------|
|                           | Lower                   | Higher |        |
| Mobility scores           | -0.641                  | -0.397 | 0.617  |
| Self-care scores          | -0.593                  | -0.349 | 0.512  |
| Usual activities scores   | -0.628                  | -0.351 | -0.527 |
| Pain/discomfort scores    | -0.462                  | -0.169 | -0.356 |
| Anxiety/depression scores | -0.511                  | 0.163  | -0.418 |
| EQ-VAS score              | 0.451                   | 0.722  | 0.649  |

## DISCUSSION

This study aimed to evaluate the effects of physical exercise on elderly HRQoL in a group of functionally independent older people without cognitive disorders. Elderly with cognitive disorders were excluded because this disorder could influence the capability for supporting correct answers. Previous studies has taken same ruling (20, 21). The elderly were included in the study as the reliance influences the HRQoL evaluation, because their functional performance could affect it (20). In this study, HRQoL was explored as the elderly were independent and had no cognitive impairments. Therefore, this study was contributed to supply high comprehensive awareness of what factors more functionally distant are related to HRQoL in elderly people. Findings of this study may be beneficial in knowledge of the efficient assessment procedures to support the ideal lifestyle of the elderly people.

Thirty minutes walking had seemed to be directly associated with positive strength of leg muscles and physical capacity in elderly subjects (22). The physical activity was concluded and determined through the waking duration in the present study as the walking is the usual physical activity in aged people and can comfortably be adapted without effort in daily life (23).

In the EuroQoL, there are two functioning and subjective well-being domains that concern the HRQoL assessment in this current study. Functioning evaluation was assessed through mobility, self-care, and usual activities dimensions. While pain/discomfort and anxiety/depression dimensions were used to assess subjective well-being evaluation. Using of Arabic version of the EuroQoL was approved to be an easy and valid measure for elderly QoL (24).

According to findings of this study, the elderly comprised 77% of the low physical activity and the greater number of elderly documented as they were diagnosed with minimum one disease. The elderly participants with low activity were reported more commonly of lasting illness as, diabetes, hypertension, and cardiovascular disease. Light sports and walking have

positive impacts to control cardiovascular disease in postmenopausal women (25).

Many previous studies approved that regular physical activity have significant improvement in health and disease control. High level of physical activity in aged people seemed an international preference (26).

The elderly participants with high activity were high scores of all EuroQoL dimensions. Functioning evaluation domain showed higher records of mobility dimension in a high physical activity group than low physical activity group ( $p < 0.05$ ). This result supports the high correlation between physical activity and HRQoL. Similar results were approved by Frandin et al as they reported that walkers have a better estimation of physical activity capacity than non-walkers (22).

Also, the elderly with high level of physical activity showed high scores of self-care and usual activities dimensions mentioned in EuroQoL. These two dimensions helped to improve the level independence and physical activity promoting reduction of disability risks in aged people (27). So, the present study investigated the relation between the level of physical activity and functioning domain variables.

In subjective well-being evaluation domain using pain/discomfort and anxiety/depression dimensions, most of all participants in this study showed slight pain/discomfort and slight anxiety/depression. There were significant differences in subjective well-being variables in high levels of physical activity compared with low physical activity level. In agreement with previous studies, the present study approved beneficial effects of physical activity on depression status and pain in elderly people (28, 29).

## CONCLUSION

It was concluded that the high level of physical activity has a beneficial effect on all dimensions of the HRQoL in elderly people. Effort and awareness should be dedicated to encouraging the active lifestyle among different population especially elderly people.

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## Declaration of interest

The authors declare no competing interests.

## Abbreviations

**BMI** — body mass index

**HRQoL** — related quality of life

**EQ-5D-3L** — EuroQol-5dimensions-3levels scale questionnaire

**EQ-VAS** — EQ visual analogue scale

## Sažetak

# POVEZANOST NIVOVA FIZIČKE AKTIVNOSTI I KVALITETA ŽIVOTA KOD STARIH OSOBA: STUDIJA PRESEKA

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**Cilj:** Cilj ove studije bio je da se ispita povezanost nivoa fizičke aktivnosti i kvaliteta života kod starih.  **Dizajn:** U periodu od januara do aprila 2017. godine, studija preseka je izvedena, i obuhvatala je 114 starih ljudi (73 muškarca i 41 žena). Srednja starosna dob je iznosila ( $71 \pm 5.24$ ) i srednja vrednost indeksa telesne mase (BMI) bila je  $29 \pm 3.31$ . Učesnici studije su bili podeljeni na osnovu distance koju su mogli da prepešače u dve grupe – niskoaktivnu grupu (distance < 150 min/nedeljno) i visoko aktivnu grupu (distance > 300 min/nedeljno). Kvalitet zdravstvenog aspekta života je meren korišćenjem Euro Qol-5 dimension-3 level upitnika (EQ-5D-3L). Statistička analiza je korišćena da ispita povezanost fizičke

aktivnosti i HRQoL skorova kod starih osoba.  **Rezultati:** Merenja su pokazala statistički značajnu razliku između visoko- i nisko aktivnih grupa ( $p < 0.05$ ). Visoko aktivna grupa je pokazala viši HRQoL skor nego niskoaktivna grupa u svih 5 dimenzija. Niskoaktivna grupa je pokazala visoku zastupljenost hroničnih bolesti.  **Zaključak:** Viši nivo fizičke aktivnosti je imao bolji efekat na sve dimenzije HRQoL kod starih osoba. Napor i svest o fizičkoj aktivnosti treba da budu posvećeni ohrabrenju da se usvoje novi aktivni stilovi života među različitim populacijama, naročito kod starih ljudi.

**Ključne reči:** stari, fizička aktivnost, HRQoL, EuroQoL.

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## ADDITIONAL EFFECT OF TRIGGER POINT THERAPY AND MYOFASCIAL RELEASE ON SECOND STAGE FROZEN SHOULDER AMONG INDUSTRIAL WORKERS

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**Abstract: Background and Purpose:** Frozen shoulder is a common condition commonly affecting 2-5% of the industrial population typically between 40 and 60 years of age. Most of the studies were analysed the individual interventions and did not investigate the combination of interventions. The purpose of this study is to find two different forms of massage techniques Trigger Point therapy and Myofascial release in second stage of Frozen Shoulder to reduce pain and improve the Range of motion. **Subjects:** 30 subjects working in industry with unilateral second stage frozen shoulder lasting 3 months or more and 25% decrease in passive joint mobility relative to the non affected side were enrolled in this study. **Methods:** Subjects who were willing to participate in the study and to fulfil the inclusion and exclusion criteria were included in the study and they were divided into two Groups (A and B) randomly. Group A was treated with Trigger Point therapy, Myofascial release, Scapula Stabilization Exercises, and Interferential Therapy (IFT) and Group B were treated only with Scapula Stabilization Exercises and IFT. The duration of treatment was 4 weeks and they were assessed at baseline and after 4 weeks. Outcome measures included pain intensity by Visual Analog Scale (VAS) and Range of Motion (ROM) by goniometer. **Results:** Subjects in both Groups improved over 4 weeks after intervention. Significant ( $p \leq 0.05$ ) difference were found between both Groups after 4 weeks in VAS and ROM. But statistically ( $p \leq 0.05$ ) greater change scores were found in the Group A for VAS and ROM than Group B. **Discussion and Conclusion:** Group A and B was effective in reducing pain and improving the ROM in patients with second stage of Frozen Shoulder. However, subjects in Group A, who re-

ceived Trigger Point therapy and Myofascial release showed better improvement in reduce pain and improve the ROM than Group B. In conclusion the treatment program consisting of Trigger Point therapy and Myofascial release may be more effective in reducing pain and improving the ROM in second stage Frozen Shoulder among industrial workers.

**Keywords:** Frozen Shoulder, Trigger point therapy, Myofascial release therapy, Interferential therapy, Visual analogue scale, Range of motion, industrial workers.

### INTRODUCTION

“Frozen shoulder” was first described by Duplay in 1872 but Codman in 1934 introduced the term frozen first time. He described painful shoulder as a condition of insidious onset that was associated with stiffness and difficulty in sleeping on the affected side. Nevisar described (1945) both the terminologies adhesive capsulitis and frozen shoulder are generally thought to be same. It is commonly affecting 2-5% of the industrial population typically between 40 and 60 years of age (1). The non-dominant arm is more likely to be involved (2), although about 12% of people are affected bilaterally (3). Other factors such as depression, immunologic factors, posture and occupation have been implicated in the aetiology (4).

Biochemical changes include alteration in immunoglobulin level and micro vascular supply of the supraspinatus tendon, with changes in the infracted tendon. Dense adhesions are present between the humeral head and the glenoid cavity. Adhesions increases as the disease progresses. The interval between the humeral

head and the glenoid gets progressively narrowed capsular contracture is noticed. The dependent fold of the capsule gets obliterated with adhesions. The synovium is thickened, reddish and edematous. It has been found that volume of the joint is reduced, and the joint capsule is tight and contracted. It generally contracts the coracohumeral ligament and the shortened coracohumeral ligament restricts the external rotation (5).

The most commonly affected movements were external rotation and abduction of the gleno-humeral joint. Patients commonly complain of sharp pain reaching for the back pocket, combing the hair or dressing and decrease arm swing when walking (6). At rest the arm is often held in adduction and internal rotation, and the scapula of the affected side is usually elevated, laterally rotated and abducted (7).

Reeves have described frozen shoulder passes through three phases such as freezing, frozen and thawing. **Phase I- Pain:** Patients have a gradual onset of diffuse shoulder pain, which is progressive over weeks to months. The pain is worse at night and is exacerbated by lying on the affected side. As the patient uses the arm less, pain leading to stiffness ensues. **Phase II- Stiffness:** Patients seek pain relief by restricting movement. This heralds the beginning of the stiffness phase, which usually lasts 4 to 12 months. Patients describe difficulty with activities of daily living. As stiffness progresses, a dull ache is present nearly all the time (especially at night), and this often is accompanied by sharp pain during range of motion at or near the new end points of motion. **Phase III- Thawing:** This phase lasts for weeks or months, and as motion increases, pain diminishes. Without treatment motion return is gradual in most, but may never objectively return to normal, although most patients subjectively feel near normal, perhaps as a result of compensation or adjustment in ways of performing activities of daily living.

Lundberg developed a classification system of frozen shoulder based on the presence or absence of an inciting event. **Primary Frozen shoulder:** A condition in patients who report no inciting event and with no abnormality on examination (other than loss of motion) or plain radiographs. **Secondary Frozen shoulder:** A condition in patients with precipitant traumatic shoulder. An important feature of adhesive capsulitis is the decreased joint capacity. Normally, 16 cm<sup>3</sup> of dye solution can be injected without resistance (8). A decreased joint capacity (less than 15 cm<sup>3</sup>) in combination with the characteristic restrictions of range of motion of the shoulder in lateral rotation, flexion in the sagittal plane, and abduction confirms the diagnosis of adhesive capsulitis (9).

Plain radiographs are usually unremarkable; there is normally an absence of bony X-ray changes. MRI has shown an increased blood flow to the synovium (10).

Treatment options include supervised physical therapy, non steroidal anti inflammatory medications, oral corticosteroids, intra-articular steroid injections, distention arthrography, closed manipulation, open surgical release, and arthroscopic capsular release. Initial treatment is non operative, with control of pain and inflammation, transcutaneous electrical nerve stimulation, and ultrasound may be helpful, combined with passive and active range-of-motion exercises (10).

Various techniques of massage and electrotherapeutic modalities produced positive outcome in patient with mixed shoulder disorders. Though individual effects of different treatment modalities are discussed in various studies, there is lack of evidence in understanding the combined effect of Trigger Point therapy and Myofascial release with physiotherapy methods. Thus the purpose of the study is to find out if there is any additional effect of Trigger Point therapy and Myofascial release when combined with conventional physiotherapy for second stage Frozen Shoulder to reduce pain and improve the range of motion.

## METHODS

A Quasi Experimental Design [Comparative study] was conducted with random sampling method. Study was done on industrial workers with second stage frozen shoulder. Thirty (n = 30) subjects who fulfilled the inclusion and exclusion criteria were included and they were divided into two groups randomly (by flipping the coin). Group A was treated with Trigger Point therapy, Myofascial release, Scapula Stabilization Exercises, and Interferential Therapy (n = 15) and Group B was treated with Scapula Stabilization Exercises, and IFT only, (n = 15) and treated for 6 sessions/ week for 4 weeks.<sup>4</sup> Study was done in Out Patient Department of Physiotherapy, C.U. Shah physiotherapy college, Surendranagar, Gujarat, India.

Subjects for the study were selected based on the following inclusion criteria, having painful stiff shoulder for at least 3 months, limited ROM of shoulder joint (ROM losses of 25% or greater) in gleno humeral flexion, abduction, medial and lateral rotation, age group between 40-60 years, both genders, and Second Stage of Frozen Shoulder (11). Exclusion criteria consists of history of surgery on the particular shoulder, rheumatoid arthritis, painful stiff shoulder after severe trauma, fracture of the shoulder complex, rotator cuff rupture, tendon calcification, diabetes mellitus, intra articular steroid injection, first and third stage of Frozen shoulder and Osteoarthritis (12).

Visual analogue scale (VAS) (Qualitative Outcome) and shoulder Range of Motion (Quantitative Outcome) as outcome measurements were taken before

and after the Program Schedule. The VAS was used to measure the Subject's current level of pain intensity. Visual analogue scale (VAS) involves a 10-cm horizontal line with "No pain" anchored at the left end and "Pain as bad as it could be" anchored at the right end. The patient was asked to place a mark on the line that represented the severity of his or her pain at the moment. The range of motion of the affected shoulders was assessed actively with a universal double-armed goniometer by placing the subjects in supine lying position. The measurements were taken for shoulder flexion, abduction, internal rotation and external rotation. Pain intensity and ROM were evaluated before and after treatment with VAS and Universal Goniometer.

### Procedure

A total number of 45 subjects were screened out of which 30 subjects were selected for the study. Each subject was screened initially by using a simple selection proforma relevant to the inclusion and exclusion criteria. Those who fulfilled this selection criterion underwent a detailed physical examination of the shoulder for baseline assessment. Then the selected patients were randomly divided (flipping the coin) into two Groups of 15 each in Group A and B. The details and the purpose of the study were explained to all the patients and informed consent was obtained from each patient. The techniques are performed by specially trained physiotherapist for Trigger point therapy and myofascial release therapy.

The study has been approved by the institutional scientific and ethical committee. All the participants completed all the sessions of intervention (no drop outs). During the treatment sessions none of the patient's experienced any adverse effects.

**Trigger Point Therapy (TPT):** 15 minute/ sessions, 6 sessions per week, – 4 weeks.

Subjects were asked to free from upper clothing and positioned comfortably in prone with both hands keep it under the head. Ischemic pressure is applied to the trigger points of supraspinatus, infraspinatus, teres major, and teres minor muscles. Apply firm digital ischemic compression to the trigger points sufficient to produce localized discomfort/pain as well as symptoms in the target area maintain this compression for 5 seconds (13). Release for 2-3 seconds. Reapply pressure (same level) and keep repeating it for 5 seconds. Two-three seconds off until the client reports a reduction in local or referred pain or an increase in pain (which is rare) or until 2 minutes have passed with no change in the pain levels. Repeat 1-3 for up to one minute and going deeper each time.

**Myofascial release (MFR):** 15 minute/ sessions, 6 sessions per week, – 4 weeks.

After the muscles and trigger points have been released the whole area is revisited for fascial restrictions. Fascia is the membrane that surrounds entire muscles, muscle fibers, fibrils and smaller structures down to cellular level. There are numerous situations where fascia restricts movement without pain, in some cases of Frozen Shoulder. MFR uses specific techniques to release fascia, deep down into the joint (14). Land on the surface of the body with appropriate žtool' (knuckles, or forearm). Sink into the soft tissue. Contact the first barrier/restricted layer. Put in a žline of tension. Engage the fascia by taking up the slack in the tissue. Finally, move or drag the fascia across the surface while staying in touch with the underlying layers. Exit gracefully. Apply for 5seconds on and 2-3 seconds off until the client reports a reduction in local pain until 2 minutes.

**Interferential Therapy:** 6 days per week for 4 weeks.

It is one of the electrotherapeutic modality mainly applied for pain reduction. Instrument used is Biotech, India and 4 electrodes are placed around the shoulder with electrode gel. Carrier Frequency 3.85 KHz and Pulse Duration 130 ms was set and it was applied for 20 minutes.

**Scapular stabilization Exercise:** 15min/session, 6 session/week-4 weeks.

Prone row exercises, Overhead arm rise in line with lower trapezius muscle, Shoulder horizontal extension with external rotation, Perform 3 sets of exercise with low intensity (40 % of maximum) for 30 repetitions with rest period of 1 minute.

### Statistical Analysis

Descriptive statistics was done in the form of mean and standard deviation. Inferential statistics evaluated changes in VAS and ROM using unpaired t-test between the two groups and paired t-test was used to measure changes within group, analysis was done using SPSS version 18.0 (SPSS, Chicago, IL). Significance was accepted with  $p < 0.05$ .

## RESULTS

**Gender distribution:** The gender distribution among 30 subjects who participated in Group A have 7 males (23.33%) and 8 females (26.67%) and Group B have 6 males (20%) and 9 females (30%).

**Age distribution:** Age distribution among 30 subjects in both Group A and B is 51.6 and S.D  $\pm$  4.561.

**Inter-group comparison of Pre VAS of Group A and B:** After analysing the data calculated U - value is 116.50, and table U - value is 64, the results shows that

calculated U - value is greater than table U - value ( $p = 0.882$ ), showing that there is no significant difference between pre values of VAS score of Group A and B score, so it shows that baseline data are homogenous.

**Inter-group comparison of Post VAS of Group A and B:** After analyzing the data the calculate U - value is 39.000, and the table U - value is 64, the results shows that calculated U - value is less than table U - value showing that there is significant difference between post values of ROM of Group A and Group B VAS score. When comparing the percentage in reduction in VAS score, Group A shows 66.62 % reduction in pain score compare to Group B 54.57 %.

**Pre and Post Values VAS of Group A and Group B:** For group A the mean of base line score of VAS is 7.40 and after 4 weeks the mean is 2.47. For group B the base line means is 7.33 and after 4 weeks the score is 3.33, it shows that there is reduction in VAS at the end of 4 weeks of treatment when compared to the first day. In Group A p-values is 0.001 and in Group B p-value is 0.000 in both the group ( $p \leq 0.05$ ), showing that p value is significant. Statistical analysis shows in Group A 66.62% reduction in pain score and in Group B 54.57% reduction in pain score.

**Inter- group comparison of Pre ROM of Group A and B:** After analyzing the data the calculate t - value for flexion is 0.5472, for abduction 0.2717, for internal rotation 1.670, for external rotation 1.376, and the table t - value is 2.048, the results shows that calculated t - value is less than table t value ( $p > 0.05$ ) showing that there is no significant difference between pre values of ROM of Group A and Group B scores, so it shows that baseline data are homogenous.

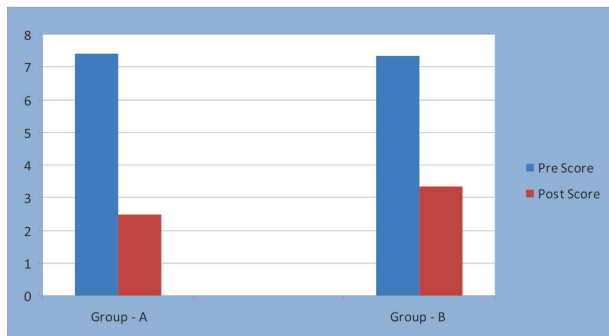
**Inter- group comparison of Post ROM of Group A and B:** After analyzing the data the calculate t va-

lue for flexion 3.443, for abduction 2.706, for internal rotation 2.737, for external rotation 4.679, and the table t - value is 2.048, the results shows that calculated t - value is greater than table t - value showing that there is significant difference between post values of ROM of Group A and Group B scores. Statistical analysis shows in Group A 38.46% improvement in flexion, 22.98% improvement in abduction, 36.22% improvement in internal rotation, and 20.94% improvement in external rotation, where as in Group B shows 27.28% improvement in flexion, 17.14% improvement in abduction, 21.46 % improvement in internal rotation, and 11.83 % improvement in external rotation. When comparing the percentage in improvement in ROM between Group A and Group B, shows there is more increase in ROM in Group A at the end of the treatment (after 4 weeks) compare to Group B.

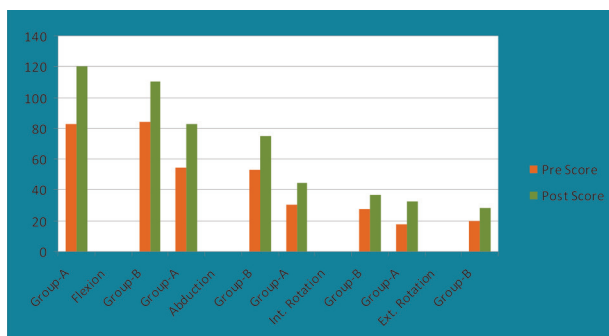
**Pre and Post Values of ROM of Group A:** The mean of base line of flexion is 82.93 and after 4 weeks the mean is 120.26. For abduction base line mean is 54.13 and after 4 weeks it is 83.06, For internal rotation base line mean is 30.60 and after 4 weeks it is 44.87, for external rotation the base line means is 17.40 and after 4 weeks it is 32.60 it shows that there is improvement in range of motion at the end of 4 weeks of treatment when compared to the first day in all the ranges. After analyzing the data the calculate t - value for flexion is 24.659 , for abduction is 20.292, for internal rotation is 23.883 ,for external rotation is 27.448 , and the table t - value for all ROM is 2.145 , the results shows that calculated t - value is greater than table t - value ( $p \leq 0.05$ ), showing that there is a significant difference between the scores in pre and post test scores of Group-1. Statistical analysis shows 38.46% improvement in flexion, 22.98% improvement in abduction, 36.22% improvement in inter-

**Table 1.** Pre and post values of pain intensity and shoulder range of motion of Group A and Group B

| Study variables        | Group | Baseline   | 4 weeks | Percentage of Improvement | p-values      |              |
|------------------------|-------|------------|---------|---------------------------|---------------|--------------|
|                        |       | Mean value |         |                           | Between group | Within group |
| Pain Intensity (VAS)   | A     | 7.40       | 2.47    | 66.62 %                   | 0.001         | 0.001        |
|                        | B     | 7.33       | 3.33    | 54.57 %                   |               |              |
| Shoulder flexion ROM   | A     | 82.93      | 120.26  | 38.46 %                   | 0.001         | 0.001        |
|                        | B     | 84.47      | 110.53  | 27.28 %                   |               |              |
| Shoulder Abduction ROM | A     | 54.13      | 83.06   | 22.98 %                   | 0.001         | 0.001        |
|                        | B     | 53.13      | 74.87   | 17.14 %                   |               |              |
| Shoulder Int. Rot ROM  | A     | 30.60      | 44.87   | 36.22 %                   | 0.001         | 0.001        |
|                        | B     | 27.73      | 36.80   | 21.46 %                   |               |              |
| Shoulder Ext. Rot ROM  | A     | 17.40      | 32.60   | 20.94 %                   | 0.001         | 0.001        |
|                        | B     | 19.60      | 28.26   | 11.83 %                   |               |              |



**Figure 1.** Pre and Post Mean of Visual Analog Scale score of Group A and B



**Figure 2.** Pre and Post Mean of Shoulder flexion, Abduction, Int. rotation and Ext. rotation range score of Group A and B

nal rotation, and 20.94% improvement in external rotation in Group A from the initial value.

**Pre and Post Values of ROM of Group B:** The mean of base line of flexion is 84.47 and after 4 weeks the mean is 110.53. For abduction base line mean is 53.13 and after 4 weeks it is 74.87, For internal rotation base line mean is 27.73 and after 4 weeks it is, 36.80 for external rotation the base line mean is 19.60 and after 4 weeks it is 28.26 it shows that there is improvement in range of motion at the end of 4 weeks of treatment when compared to the first day in all the ranges.

After analyzing the data the calculate t - value for flexion is 70.226 for abduction is 58.551, for internal rotation is 16.060, for external rotation is 19.255, and the table t - value for all ROM is 2.145, the results shows that calculated t - value is greater than table t value ( $p \leq 0.05$ ), showing that there is a significant difference between the scores in pre and post test scores of Group B. Statistical analysis shows 27.28% improvement in flexion, 17.14% improvement in abduction, 21.46 % improvement in internal rotation, and 11.83 % improvement in external rotation in Group B from the initial value (Table 1, Figure 1 and 2).

## DISCUSSION

Frozen Shoulder is characterized by painful stiffness of the shoulder that may persist for several years.

It is a common disorder; with an estimated annual incidence of 3% to 5% in the industrial population (15). Advocated treatments include rest and analgesics, corticosteroid injections, acupuncture, physical therapy, manipulation under anaesthesia, and arthroscopic or open surgery. There is no general acceptance of one standard treatment.

The study was conducted on 30 patients with two groups of 15 each. Group A was intervened with Trigger Point therapy, Myofascial release, Scapula Stabilization Exercises, IFT whereas Group B was intervened with Scapula Stabilization Exercises and IFT only. Outcome measures measured Pain Intensity by Visual Analog Scale and Range of Motion by goniometer measured prior to treatment (Pre-Rx) and at the end of 4 weeks of treatment.

1<sup>st</sup> objective of this study was to find the effectiveness of trigger point therapy and myofascial release combined with IFT, and scapula stabilization exercises in second stage of frozen shoulder to reduce pain and improve the range of motion. In Group A its overall effectiveness on VAS score was found using Wilcoxon test, after 4 weeks of treatment which shows p value = 0.001, which is significant. ROM was found using paired t-test which shows p = 0.000 which is very highly significant for all shoulder ranges after 4 weeks of treatment. This suggests that trigger point therapy and myofascial release combined with conventional treatment is effective in reducing pain and improving the Range of motion.

The 2<sup>nd</sup> objective of this study was to find the effectiveness of Scapula Stabilization Exercises and IFT on second stage frozen shoulder. In Group B subjects who received Scapula Stabilization Exercises and IFT its overall effectiveness on VAS score was found using Wilcoxon test after 4 weeks of treatment which shows p = 0.001, which is significant. ROM was found using paired t-test which shows p = 0.000 which is significant for all shoulder ranges after 4 weeks of treatment. This suggests that conventional treatment is effective in to reduce pain and improve the Range of motion.

The 3<sup>rd</sup> objective of the study was to compare the effectiveness of Trigger point therapy, Myofascial release, Scapula Stabilization Exercises and IFT (Group A) over Scapula Stabilization Exercises and IFT (Group B) in the management of second stage frozen shoulder. The intergroup comparison of VAS Score was done using Mann Whitney test which showed 'p' significant after four weeks of treatment, Comparison of ROM of both Group A and Group B was done using independent t-test which showed 'p' value significant for all the ranges.

Statistical analysis shows when comparing the percentage of reduction in VAS score between Group

A and Group B, Group A shows 66.62 % reduction in pain score when compare to Group B (54.57 %). Statistical analysis shows in Group A 38.46 % improvement in flexion, 22.98% improvement in abduction, 36.22% improvement in internal rotation, and 20.94% improvement in external rotation, where as in Group B 27.28% improvement in flexion, 17.14% improvement in abduction, 21.46 % improvement in internal rotation, and 11.83 % improvement in external rotation. When comparing the percentage in improvement in ROM between Group A and Group B, Group A shows more increase in ROM at the end of the treatment (after 4 weeks) compare to Group B.

The results of this study supported the experimental hypothesis that there is significant difference between the Trigger Point therapy and Myofascial release combined with conventional treatment versus conventional treatment alone in the treatment of second stage of Frozen Shoulder. On further analysis it also supported the hypothesis that there is significant difference in effectiveness of Trigger Point therapy and Myofascial release combined with conventional treatment versus conventional treatment alone in the treatment of second stage of frozen Shoulder.

Our results support the study of Susan Jackson et al conducted a study on frozen shoulder treatment of the myofascial release at Auburn Hospital and Concord Repatriation General Hospital in Sydney, Australia; over second stage frozen shoulder patients (n = 29), with help of MFR And Trigger point therapy and concluded that following a, Soft-tissue massage improved range of motion, reduced pain and improved function in people with shoulder pain (13). S Niel-Asheret al conducted a study on Frozen Shoulder Syndrome: a novel manipulative approach at the London frozen shoulder clinic (private); over Second stage frozen shoulder patients (n = 100) with help of soft tissue treatment (MFR) concluded that this technique may have a significant role in improved range of motion, reduced pain the management of frozen shoulder syndrome (16).

In Trigger Point Therapy, ischemic pressure may be applied to the trigger points in the painful area (13). Pressure on the trigger point stops blood from flowing into the affected area making it ischemic (deprived of oxygen) (13). The person should feel a “comfortable pain” as if pressure is being released. After 5 seconds the pressure is released and the circulation of blood, oxygen and nutrients to the area increases (13). In addition, it is important to apply general massage to the surrounding muscles of the shoulder, this helps keep the shoulder functioning correctly and speeds up the reha-

bilitation process (13). From this study it can be said that Trigger Point therapy and Myofascial release combined with conventional treatment can be used as additional method of choice for the treatment of patient with frozen shoulder.

## CONCLUSION

The results indicate that both experimental and control groups are effective in the second stage of Frozen Shoulder to reduce pain and improve the Range of motion. However, the subjects in the experimental group, who received Trigger Point therapy and Myofascial release showed better improvement in reducing pain and improving the ROM than the control group. In conclusion the treatment program consisting of Trigger Point therapy and Myofascial release may be more effective in the second stage of Frozen Shoulder to reduce pain and improve the Range of motion among industrial workers.

## Limitations of the study

The main limitation of this study was its small sample size. A larger sample would be required to validate and generalize the results of this study to the population. Further the design did not support long-term follow-up of the patients after the study, to understand the long term benefits even after completion of the study.

## Recommendations for future study

The effectiveness of other types of exercise programs can be trailed and the same study can be done with a longer follow-up. Other outcome measures such as functional level, depression status and quality of life can also be measured in the future study.

## Acknowledgement

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## Declaration of interest

The authors declare no competing interests.

## Abbreviations

**IFT** — Interferential Therapy

**VAS** — Visual Analog Scale

**ROM** — Range of Motion

## Sažetak

## DODATNI EFEKAT TERAPIJE TAČAKA OKIDANJA I TEHNIKE MIOFASCIJALNOG OSLOBAĐANJA NA DRUGI STADIJUM SMRZNUTOG RAMENA MEĐU INDUSTRIJSKIM RADNICIMA

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**Uvod i cilj:** Sindrom smrznutog ramena je često stanje koje obično zahvata 2-5% industrijske populacije, tipično između 40-60 godina starosti. Većina studija je analizirala na osnovu pojedinačne intervencije, i nije ispitivala kombinacije intervencija. Cilj ovog rada bio je da se ispituju dve različite tehnike masaže, terapija tačke okidanja i tehnika miofascijalnog oslobađanja, u drugom stadijumu smrznutog ramena, kako bi se smanjili bolovi i povećala širina pokreta. **Pacijenti:** U studiju je uključeno 30 osoba koje su radile u industriji sa unilateralnim smrznutim ramenom u drugom stadijumu, koje je trajalo 3 ili više meseci unazad i sa padom pasivne pokretljivosti zglobova u iznosu od 25% ukupne pokretljivosti zglobova u poređenju sa pokretljivošću ramena druge strane. **Metode:** Pacijenti koji su ispunjavali kriterijume su svojevremeno pristali da učestvuju u studiji, i bili su nasumično raspoređeni u dve grupe, A i B. Grupa A je bila lečena terapijom tačke okidanja, tehnikom miofascijalnog oslobađanja, vežbama stabilizacije skapule i interferentnom terapijom (IFT), a Grupa B je lečena samo vežbama stabilizacije skapule i IFT. Dužina tretmana je bila 4 nedelje, i stepen pokretljivosti zglobova je bio procenjivan na početku i 4 nedelje nakon početka od-

govarajuće terapije. Ishodna merenja su uključivala Analog Vizuelne Skale (VAS) i opseg pokreta (ROM) pomoću goniometra. **Rezultati:** Pacijenti obe grupe su napredovali tokom 4 nedelje nakon intervencije. Značajna razlika je nađena prilikom poređenja obe grupe nakon 4 nedelje i u VAS i u ROM parametru. Ali, statistički značajno veći skor promene je nađen u Grupi A za VAS i ROM nego u grupi B. **Diskusija i zaključak:** Tretman primenjen na grupama A i B bio je efektan u smanjenju bola i u popravljaju opsega pokreta (ROM) kod pacijenata u drugom stadijumu smrznutog ramena. Međutim, pacijenti grupe A, koji su imali terapiju tačke okidanja i tehniku miofascijalnog oslobađanja, pokazali su bolji napredak u smanjenju bola i napredovanju ROM nego u Grupi B. U zaključku se može reći da tretman koji je činila terapija tačke okidanja i tehnika miofascijalnog oslobađanja je efektivnija u smanjenju bola i popravljaju opsega pokreta u drugom stadijumu sindroma smrznutog ramena među industrijskim radnicima.

**Cljučne reči:** Smrznuto rame, terapija tačaka okidanja, tehnika miofascijalnog oslobađanja, Interferentna terapija, Vizuelno analogna skala, obim pokreta, industrijski radnici.

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## TOTAL KNEE SURGERY: OUR EXPERIENCE

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**Abstract: Introduction:** Revision knee arthroplasty is not a routine procedure and almost always it is a technically demanding operation. The paradigm in revision total knee arthroplasty is to achieve correct alignment of the components, maintenance of the joint space and ligament balance by providing a stable bone – implant fusion. Metaphyseal bone loss is a crucial problem in revision total knee arthroplasty. The bone loss is due to primary arthroplasty technical errors and design, or problematic removal of the implants.

**Aim:** The aim of this article is to present our experience on total knee revision surgery using tantalum metal cones as a structural bone graft substitute in total arthroplasty failure with gross metaphyseal bone loss categorized by the AORI classification, performed by a specific surgical technique and evaluated by the Knee Society Score (KSS).

**Material and methods:** From 2013 to 2016 at the University Clinic for Orthopedic Surgery in Skopje 21 patient has been treated with revision total knee arthroplasty. Twelve patients had type 1/type 2 bone defects according to AORI, and nine had type 3 bone defect. We used trabecular metal bone graft in type 3 bone defects. A special emphasis is placed on preoperative planning according to the classification system for ligament and soft tissue damage as well as the AORI classification in order to determine the quantity, location and extent of the bone loss. In our series in patients with type 3 deformities, trabecular metal augments were used. This material resembles the human trabecular bone by its cellular structure and elastic characteristics.

**Results:** Preoperatively, all the patients had Knee Society Score below 60, most of them were housebound, experiencing great pain and disability. After six months 95% were rated excellent, and on one year follow up, 89% were rated good or excellent (KSS score above 82, mean score 81.5), 1 patient was marked as poor with a complication – dislocation of the prosthesis. In the follow up period there was no infection.

**Conclusion:** Our results of revision knee arthroplasty by using the trabecular metal augments with at least a year of follow up are excellent according to the KSS compared to the other studies. The disadvantages of the study are mentioned and the need for further investigation is stressed.

**Key words:** Revision knee arthroplasty, metaphyseal bone loss, AORI classification, Knee Society scores, trabecular metal augments.

### INTRODUCTION

Metaphyseal bone loss is a crucial problem in revision total knee arthroplasty. The bone loss is due to primary arthroplasty technical errors and design, or problematic removal of the implants. The paradigm in revision total knee arthroplasty is to achieve correct alignment of the components, maintenance of the joint space and ligament balance by providing a stable bone – implant fusion. The management of bone loss is completed by substituting it with bone cement, autologous spongy bone grafts, autologous structural graft fragments, modular metallic boosters or thicker polyethylene components. Nonetheless, the correct treatment for large defects remains undefined and homologous structural grafts, impacted spongy grafts or unconventional prostheses can be used (1). An invention that porous tantalum – trabecular metal booster, has an excellent biocompatibility, is safe to use, and has emerged its use in revision arthroplasty as a scaffold for osseous ingrowth i.e. as a structural bone graft substitute. This material also has the characteristic of mineral density preservation of the surrounding bone making it plausible for use in elderly osteoporotic bone. According to the Anderson Orthopedic Research Institute (AORI) classification, type 2-B and type 3 defects usually require large metal blocks, bulk structural allograft or highly porous metal cones, according to an algorithm later described. Tibial and femoral trabecular metal metaphyseal cones are a unique solution for large bone

defects. These cones substitute bone loss, improve metaphyseal fixation, help correct malalignment, restore the joint line and may permit use of a shorter stem(2). The use of tantalum cones in revision arthroplasty literature has been shown to be associated with good clinical and radiological outcomes. Studies have shown that average Knee Society clinical scores (KSS) improve significantly postoperatively.

There are several reasons for total knee arthroplasty failure. The most prominent are: aseptic/septic loosening, acute trauma, unstable knee, angular, torsion deformity, pain, impaired patellar tracking, stiff knee, infection. The diagnosis is based on clinical, imaging and laboratory findings. Clinically, there is pain, instability of the knee, redness when septic loosening is suspected. We also ask if any traumatic event occurred. The clinical findings show decreased range of motion, abnormality in the extensory apparatus. From the imaging techniques plain roentgenogram usually clears the picture, in some cases additional CT or MRI can be ordered. We use blood count, sedimentation rate and CRP from the laboratory findings, we send specimens from the knee aspirate for microbiology analysis. Sometimes we order scan with Tc99m.

The authors present retrospective case series of primary total knee arthroplasty failure that were treated with tantalum cones in a revision knee arthroplasty procedure in a tertiary academic institution under a single surgeon.

## AIM

The aim of this article is to present our experience on total knee revision surgery using tantalum metal cones as a structural bone graft substitute in total arthroplasty failure with gross metaphyseal bone loss categorized by the AORI classification, performed by a specific surgical technique and evaluated by the Knee Society scores (KSS).

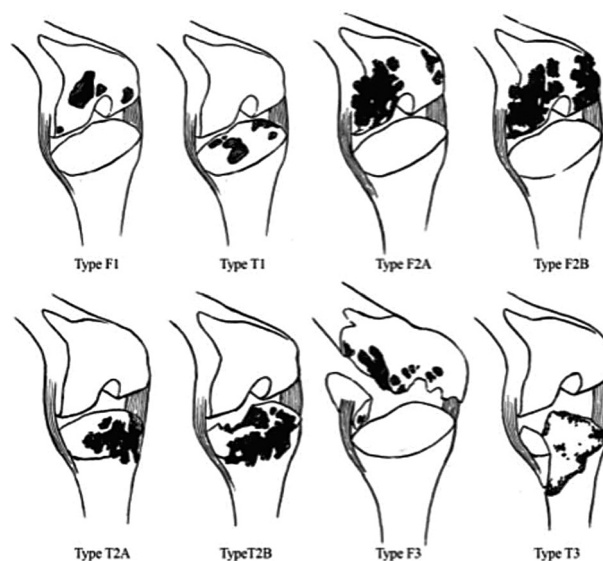
## MATERIAL AND METHODS

From 2013 to 2016, at the University Clinic for Orthopedic Surgery in Skopje, 21 patient has been treated with revision total knee arthroplasty. Twelve patients had type 1/type 2 bone defects according to AORI, and nine had type 3 bone defect. We used trabecular metal bone graft in type 3 bone defects. The surgical procedures were performed at the University Clinic for Orthopedic Surgery in Skopje. The follow up was completed immediately postoperatively, on six months and a year after the procedure, by a clinical and radiological means using the KSS and osteo-integration signs. The patients were followed for at least a year after the

procedure. In 5 patients of those with type 3 AORI defects the reason for revision was aseptic loosening, in the remaining 4 the procedure was second stage revision after an infection.

A special emphasis is placed on preoperative planning according to the classification system for ligament and soft tissue damage as well as the AORI classification (as shown in Figure 1) in order to determine the quantity, location and extent of the bone loss. In the AORI classification the femur and tibia are classified separately, as follows: type 1 – complete metaphyseal bone with small defects that would not compromise the stability of the revision implant (type F1-intact metaphyseal cortex of the femur, type T1-intact metaphyseal cortex of the tibia); type 2 – loss of spongy bone in the metaphyseal region, which could occur in one (A) or in two (B) femoral –type F2A or type F2B or tibial condyles-type T2A or type T2B; type 3 – deficient metaphyseal bone, occasionally associated with detachment of the collateral ligaments (type F3-femoral metaphyseal defect, or type T3-tibial plateau defect).

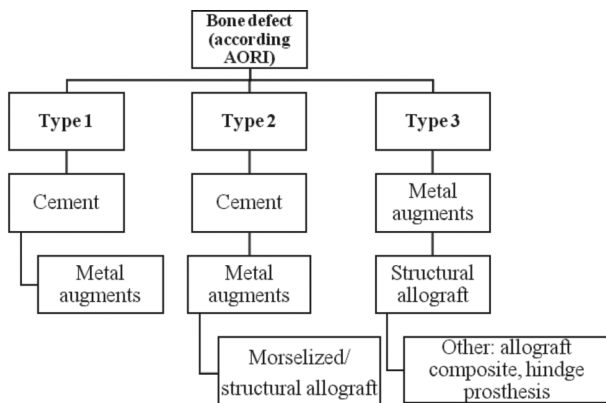
Also, ligament stability and the extensor mechanism integrity is evaluated. The ligament status is classified as stable, absent PCL, absent LCL, absent MCL and absence of all ligaments around the knee.



**Figure 1.** Anderson Orthopedic Research Institute (AORI) classification of bone defects in TKA

Usually, the real bone loss in situ surpasses the bone loss seen in the preoperative radiographs. All these steps lead to choosing the right approach for the revision, as well as obtaining the right implant, instruments, the need for bone transplants, or metal augments. In order to make the right choice of treatment we used the following algorithm (Figure 2).

Type 1 defects can be managed using cement, or in extraordinary cases, metal augments. Type 2 defects



**Figure 2.** Algorithm for proper treatment according to AORI classification

can be worked out by metal augments, or morselized or structural allografts. In order to solve the problem with type 3 defects, metal augmentation, impact grafting, structural allograft, hinge or constrained condylar prosthesis is used.

In our series in patients with type 3 deformities, trabecular metal augments were used. This material resembles the human trabecular bone by its cellular structure and elastic characteristics. By approaching the mechanical and physical characteristics of the bone, the trabecular metal consists of 80% porosity, similar to the bone, enabling fast and broad bone infiltration.

Trabecular metal tibial and femoral cone augments enable secure structural bone substitute. The design allows filling the big cavitory bone defects and consequently preparing a stable platform for femoral and tibial components. The femoral cone augment is designed to contribute the reconstruction in rotation, and the asymmetric design follows the anatomic direction of the femoral bone during centralization. Eventual gaps between the porous surface and the host bone should be filled with morselized bone allograft, autograft or bone substitutes (3). Histological studies have shown low potential for bacterial adherence with greater leucocyte activation, reducing the risk of infections (4, 5).

The tibial trabecular metal cone is used to achieve stability in the construction of the proximal part of the calf where small to medium bone cavities are present. The tibial cone allows strengthening of the medular cavity of the tibia. Stable fixation is done by placing stem extensions for the femur and tibia.

## SURGICAL TECHNIQUE

The exposure is medial parapatellar, using a central incision; whenever possible, the previous surgical incision is used (Figure 3). The subcutaneous tissue is thick dissected in order to maintain the vascularization and avoid ischemia leading to the medial parapatellar arthrotomy (Figure 4). At this point a swab culture, or



**Figure 3.** Scar tissue of the previous surgical interventions is used again in this patient



**Figure 4.** Thick dissected subcutaneous tissue

synovial fluid for microbiology assessment is obtained. Lateral parapatellar approach can be used in angular (valgus) deformities.

All the granulation tissue, necrotic tissue or evidence of infection should be removed, followed by wide debridement. In a case of infection evidence, the procedure is stopped and antibiotic impregnated polymethylmethacrylate spacer is introduced, the wound is closed and negative cultures are expected. Removal of the components can be difficult even if the reason for revision is component loosening. All soft tissue must be removed from the bone or the components. There are specific instruments for component removal that can be used in difficult extraction, or the removal can be achieved by using an osteotome. Sometimes it



**Figure 5.** MMA spacer removal



**Figure 6.** Tibia after the cement spacer removal, debridement of cement and granulation tissue

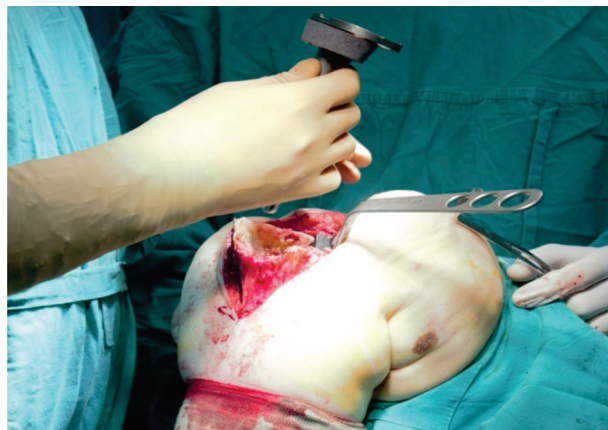


**Figure 7.** Tibia after the cement spacer removal, debridement of cement and granulation tissue

can be challenging to leave all the underlying bone intact which leads to iatrogenic bone loss. We usually remove the tibial component first and then the femoral component. A thorough removal of necrotic bone, debris, necrotic tissue and cement remaining is mandatory (Figure 5, 6 and 7).

Next step after we've reached a clear picture is the task to reconstruct the knee. Even though almost always it is not an easy duty, the imperative is to recreate an arthroplasty that is kinematically well adjusted. Reconstruction is approached using a three-step method: 1. re-create the flat tibial surface, 2. re-create the femur and rebuild the flexion space, and 3. rebuild the extension space (6). The cornerstone of rTKA is building a flat perpendicular tibial surface that will serve as basis for the arthroplasty. Therefore, recreating the tibial side to its original height by using the augments and subsequently placing the appropriate polyethylene insert leads to correct flexion and extension gaps (Figure 8 and 9).

On the femoral side it is very important not to under-size the femoral component, since usually there is posterior bone loss that can be easily overseen. An undersized



**Figure 8.** Placing the tibial augment and component



**Figure 9.** Tibial component in situ

component leads to failure to restore the posterior femoral offset and compromise flexion stability. Femur component rotation is adjusted towards the remaining femoral bone (the epicondyles or the tibial plateau if severe bone loss persists). The joint line is restored by distal femur positioning (Figure 10). The reconstruction is finalized by recreating the flexion and extension space. The flexion space is completed by inserting the thickest tibial polyethylene surface that fills the flexion space (Figure 11).



**Figure 10.** Femoral component placing



**Figure 11.** Joint line in flexion



**Figure 12.** Joint line in extension

An attempt is made to extend the knee looking for stable and equal gaps. If we have achieved that, we expect to have a kinematically stable knee (Figure 12). Regarding design and devices, we used porous tantalum cones (Trabecular Metal™; Zimmer, Warsaw, IN, USA), Zimmer Legacy Constrained Condylar Knee (LCKK) or Zimmer Next Gen Rotating Hinge Knee (RHK).

## RESULTS

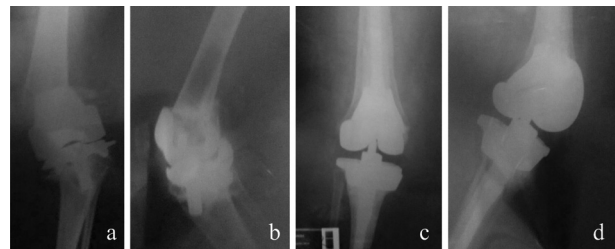
We used the Knee Society score to evaluate the results preoperatively, on six months and a year after the procedure. We also used radiological means estimating the osteo-integration signs, obtaining radiologic images immediately postoperatively, on six months and after a year.

The Knee Society Score is a clinical rating system developed in 1989 and is consisted of an evaluation form subdivided in a knee score that rates only the knee joint itself and a functional score that rates the patient's ability to walk and climb stairs (7). The grading for the knee Society Score is: score of 80-100 as an excellent outcome, score 70-79 a good outcome, score 60-69 fair outcome and score below 60 as a poor outcome.

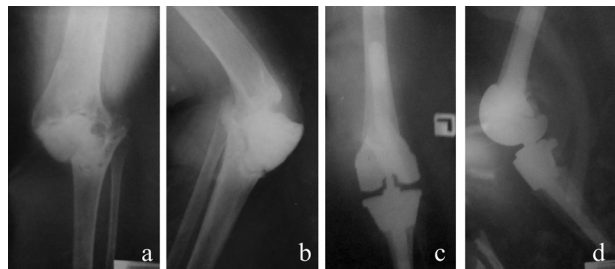
Preoperatively, all the patients had score below 60, most of them were housebound, experiencing great pain and disability. After six months 95% were rated excellent, and on one year follow up, 89% were rated good or excellent (KSS score above 82, mean score 81.5), 1 patient was marked as poor with a complication – dislocation of the prosthesis. In the follow up period there was no infection.

All patients were followed for at least a year (mean follow up of 28 months) (Table 1).

Radiographically we didn't encounter subsidence or signs of failure in all the images (Figures 13, 14, 15). No radiolucencies were identified on the bone-tanta-



**Figure 13.** Case 1: a) and b) preoperative radiographs; c) and d) postoperative radiographs



**Figure 14.** Case 2: a) and b) preoperative radiographs; c) and d) postoperative radiographs

**Table 1.** Revision total knee arthroplasty results in patients with type 3 defects according AORI

| Case | Age | Gender | Follow-up (months) | Stage by AORI classification | Postoperative KSS |
|------|-----|--------|--------------------|------------------------------|-------------------|
| 1    | 79  | F      | 48                 | F2B T3                       | 79                |
| 2    | 75  | F      | 44                 | F3 T3                        | 85                |
| 3    | 69  | M      | 39                 | F3 T2A                       | 89                |
| 4    | 79  | F      | 32                 | F3 T3                        | 55                |
| 5    | 66  | F      | 27                 | F2A T3                       | 83                |
| 6    | 72  | F      | 24                 | F3 T3                        | 84                |
| 7    | 77  | M      | 18                 | F2A T3                       | 87                |
| 8    | 69  | M      | 13                 | F3 T3                        | 90                |
| 9    | 70  | F      | 12                 | F2B T3                       | 82                |



**Figure 15.** Case 3: a) preoperative radiographs; b) and c) postoperative radiographs

lum interface and there was no migration of the femoral or tibial components.

## DISCUSSION AND CONCLUSION

Revision knee arthroplasty is not a routine procedure and almost always it is a technically demanding operation. The instruments are not as helpful as they are in the primary knee arthroplasty. The techniques for revision arthroplasty evolve continuously. Having that in mind it is hard to present consistent results since material improvement leads to better outcome (8).

Bone defects are challenge during the rTKA and there are many treatment options, that include cement filling, cement with augmentation, metal augmentation, moselised and structural bone grafts, and tantalum. Which modality will be used depends on the location and size of the bone defect, the bone quality, the surgeon's preference and material availability (9).

First published work on trabecular metal use in rTKA is the one of Radnay and Scuderi in 2006 (10). Their pioneer work with average 10 months follow up showed the good prognosis of the use in this metal in rTKA.

In their review article for treatment options for rTKA, Qiu and al. systematically show the advantages and disadvantages of all the treatment possibilities. The advantages of trabecular metal are its biocompatibility and bioactivity, the low modulus of elasticity, as well as the high frictional characteristics and a high volumetric porosity. The disadvantages are that it's not a popular choice, the lack long-term follow-up and its cost (11).

Fosco and al. in their work from 2012 stress that in the elderly, bone loss should be accomplished using artificial materials, while in younger patients, therapy should be addressed to regeneration of new bone as a foundation for future revision procedures. So that, an ideal bone substitute should possess an osteogenic, osteoinductive and osteoconductive potential (12). They also say that although the results of metaphyseal metal implants are promising, concerns still exist regarding stress shielding and difficulty of their removal. The other modalities of treatment as structural allografts and tumor megaprotheses during revision knee arthroplasty have encouraging midterm results, but there is a high number of complications such as infection,

graft resorption, nonunion, failure of graft incorporation, potential disease transmission, aseptic loosening and periprosthetic fracture (13, 14, 15).

Even though these types of operations are used for many years in the USA and Europe for about a decade, these are the first reported cases from our country that have undergone this demanding operation with implantation of expensive materials. Therefore, we present the clinical outcomes according the Knee Society score as well as radiologic findings for osteointegration.

We are aware of the limitations of this study. The patient cohort is relatively small, but not much smaller than cohorts of the previous studies, regarding the number of patients migrating in our institution (16, 17, 18). Next, the mean follow up of 28 months is short, the patients need to be followed longer in order to get the right picture of the durability of these implants. Even though we have protocol for radiologic investigation, and that is standing AP and lateral views, the quality of the radiographs differs depending on the technician experience and X-ray paper and machine quality.

The results of our study can be compared and are similar to those reported by De Martino and al. (19), Meneghini et al. (18) and Long and Scuderi (17) having an unquestionable osteointegration of the cones and similar percent for the need of reoperation. The increase of the Knee Society score in terms of pre and postoperative numbers is similar to other studies (2, 16, 20).

The use of tantalum cones in our short term study, as well as several mid-term studies have shown to be successful, adding an option for favorable outcome in these highly demanding interventions and it has become a cornerstone in the treatment of bone loss in contemporary revision surgery. Waiting for studies with longer follow up, we remain close to this technique especially in elderly patients with low demands.

## Abbreviations

**AORI classification** — Anderson Orthopedic Research Institute classification

**KSS** — Knee Society Score

**rTKA** — revision total knee arthroplasty

**PCL** — posterior cruciate ligament

**LCL** — lateral collateral ligament

**MCL** — medial collateral ligament

## CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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## Sažetak

## REVIZIONA ARTROPLASTIKA KOLENA: NAŠE ISKUSTVO

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Univerzitetska Klinika za Ortopediju u Skoplju, Republika Makedonija

**Uvod:** Reviziona artroplastika kolena nije rutinska procedura i uglavnom uvek je tehnički zahtevna operacija. Cilj revizione totalne artroplastike kolena je da se postigne tačno poravnanje komponenti, očuvanje prostora zgloba i balans ligamenata obezbeđujući stabilnu kost-implant fuziju. Metafizealni gubitak kosti je krucijalni problem kod revizione totalne artroplastike kosti. Gubitak kosti je posledica tehničke greške i dizajna primarne artroplastike ili problematičnog uklanjanja implanata.

**Cilj:** Cilj ovog rada je da prikaže naše iskustvo sa revizionom hirurzijom kolena nakon neuspele totalne artroplastike, sa značajnim metafizealnim gubitkom kosti kategorisanim AORI klasifikacijom, uz upotrebu tantal konusa i specifične hirurške tehnike, i evaluaciju pomoću skora udruženja za koleno (KSS-Knee Society Score).

**Materijal i Metode:** Od 2013. do 2016. godine, na Univerzitetnoj Klinici za Ortopediju u Skoplju, 21 pacijent je podvrgnut revizionoj totalnoj artroplastici kolena. Dvanaest pacijenata je imalo tip 1/tip2 defekt kosti prema AORI klasifikaciji, 9 je imalo tip 3. Poseban akcenat je stavljan na preoperativno planiranje na osnovu klasifikacije povreda ligamenata i mekih tkiva, uključujući i AORI klasifikaciju, s ciljem da se utvrdi

kvantitet, lokalizacija i stepen gubitka kosti. Koristili smo trabekularni metal kao koštani graft kod defekta kosti tip 3. Ovo je biomaterijal koji je po svojoj strukturi i karakteristikama elasticiteta najsljedniji strukturi trabekularne kosti.

**Rezultati:** Preoperativno, svi pacijenti su imali KSS ispod 60, većina ih je bila vezana za kuću, osećala jake bolove i imala značajan stepen nesposobnosti. Posle šest meseci kod 95% operisanih stanje je okarakterisano kao odlično, a posle godinu dana praćenja kod 85% pacijenata stanje je okarakterisano kao dobro ili odlično (KSS iznad 82, srednja vrednost skora 81,5), stanje kod 1 pacijenta je okarakterisano kao loše, sa dislokacijom proteze kao komplikacijom. U toku perioda praćenja nije bilo infekcija.

**Zaključak:** Naši rezultati revizione artroplastike kolena sa upotrebom trabekularnog metala, nakon godinu dana praćenja, okarakterisani su kao odlični prema KSS skoru u odnosu na druge studije. Nedostaci studije su opisani i naglašena je potreba za daljim istraživanjem.

**Cljučne reči:** reviziona artroplastika kolena, metafizealni gubitak kosti, AORI klasifikacija, skor udruženja za koleno, trabekularni metal.

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## OUTCOME OF MULTIVISCERAL ECHINOCOCCOSIS: A CASE REPORT

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**Abstract: Introduction:** The pathogen of multivisceral echinococcosis is the same agent as for single-organ echinococcosis: *Echinococcus granulosus*. According to the consensus of experts under the aegis of the WHO-IWGE - WHO- Informal Working Group on Echinococcosis options of treatment should be: (1) percutaneous treatment, (2) surgery, (3) anti-infective drug treatment or (4) watch and wait approach or combinations thereof.

**Case report:** The presented case was a seven-year-old Caucasian boy, a permanent resident of rural region near Tuzla, Bosnia and Herzegovina, who had a history of asymptomatic giant liver and small lung hydatid cyst (multivisceral echinococcosis). We consider that the patient was in the phase of secondary hydatidosis even before undergoing the first treatment PAIR method of liver and continued with adjunctive chemotherapy. Two weeks after discharge, during the adjunctive chemotherapy he had one of possible complication where pre-existed small lung hydatid cyst got inflamed and performed an abscess mass and potential septic risk, which required surgical and antibiotic treatment. Surgery and early postoperative course were normal and the patient was discharged with recommendation to continue with previously started adjunctive chemotherapy (Albendazol) according to treatment protocol.

**Conclusion:** Most infected persons are asymptomatic and clinical manifestations vary according to the anatomic location of the cyst, so we want to indicate the importance of routine ultrasound screening of preschool children, and eventually X ray chest scan. This case report highlights the necessity of caution with choosing appropriate treatment, even though size of cyst can be irrelevant to take surgical treatment in first line instead of medical therapy.

**Key words:** echinococcosis, hydatid cyst, hydatidosis, diagnosis, treatment.

### INTRODUCTION

Hydatid disease (cystic echinococcosis) is a parasitic infestation caused by *Echinococcus species*, the most common being *Echinococcus granulosus*; others are *E. multilocularis* and *E. vogeli*. The primary hosts are dogs while humans are accidental intermediate hosts infected through ingestion of contaminated food with dog faeces or through direct contact with dogs (1).

On the contrary to the popular perception, hydatidosis (cystic echinococcosis) does not remain restricted to endemic geographical locales anymore but is rather a global health concern, particularly in the rural countryside and semiurban localities. Most of the cases of hydatid disease come from rural areas or from people who have settled in urban localities after spending a majority of their life in villages. Many patients usually acquire the disease during childhood, but do not present with the clinical signs and symptoms until late adulthood (2).

The pathogen of multivisceral echinococcosis is the same agent as for single-organ echinococcosis: *Echinococcus granulosus*. During its lifecycle, humans are intermediate hosts in which only the larva, the hydatid cyst, with different localizations, develops. Multivisceral echinococcosis is defined as the simultaneous localization of the hydatid cysts in more than one viscera. It was differentiated from multiple echinococcosis, which means multiple localizations of the hydatid cysts inside the same viscera. The most frequently involved organs were: lungs, liver, spleen, heart, thoracic aorta, pancreas, and the kidneys. More frequent multivisceral associations were: right lung – left lung; left lung – liver; right lung – liver (3).

Errors in the clinical diagnosis of hydatid disease are frequent due to the lack of any typical clinical presentation of the disease and imaging features which

can also be variable. The symptoms of hydatid disease depend on which organs are affected. Most patients with hydatid cysts are asymptomatic, and the diagnosis usually made incidentally during clinical radiological examination for unrelated reasons (4).

The variation of clinical presentation depends on the size and site of the lesion as well as the accessibility of the organ involved in the clinical examination. Lung involvement with chest pain, cough, shortness of breath can cause non specific symptoms such as fever and hemoptysis (5).

Diagnosis is based on clinical signs, laboratory results and epidemiologic data (6).

The combined use of ultrasonography and immunodiagnosis makes possible the distinction of echinococcal cysts from benign cysts, abscesses or malignant neoplasms (7).

The standard chest X-ray is very useful and it can suggest by itself the diagnosis of pleuro-pulmonary echinococcosis. Around or oval opacity, of subcostal intensity is described. According to evolutionary stage of the hydatid cyst, the radiological aspect is described as polymorphic. The introduction of computed tomography in the diagnosis of multivisceral echinococcosis brought immense advantages. Computed tomography is useful in certifying multivisceral echinococcosis diagnosis, differential diagnosis and postoperative surveillance (3).

For cystic echinococcosis, the consensus of experts under the aegis of the WHO-IWGE - WHO-International Working Group on Echinococcosis, has been obtained on an image-based, stage-specific approach, which is helpful for choosing one of the following options: (1) percutaneous treatment, (2) surgery, (3) anti-infective drug treatment or (4) watch and wait approach or combinations thereof. Clinical decision-making depends also on setting-specific aspects. The usage of an imaging-based classification system is highly recommended (8). It is useful to establish a concept that defines multivisceral echinococcosis and guides the therapeutic management of multivisceral hydatid disease.

## CASE PRESENTATION

A seven-year-old Caucasian boy, a permanent resident of rural region near Tuzla, Bosnia and Herzegovina, presented to us for the first time with asymptomatic liver cyst found by routine ultrasound screening. He was admitted with normal vital signs and normal physical examination apart from the occurrence of herpes labialis. Laboratory investigations that were performed included a complete blood count, liver function tests and urine analysis; all results were within normal ranges. CT scan of abdomen revealed a round cystic for-

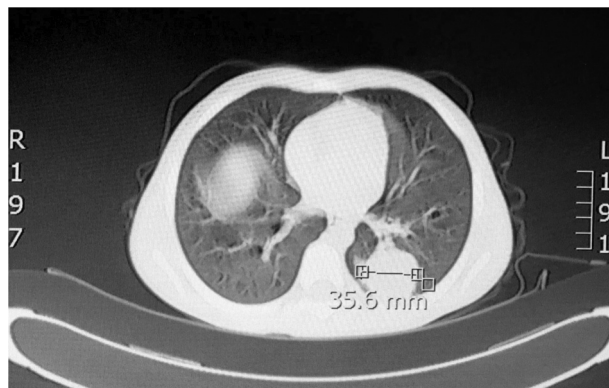


Figure 1. Cystic formation in left basal lung

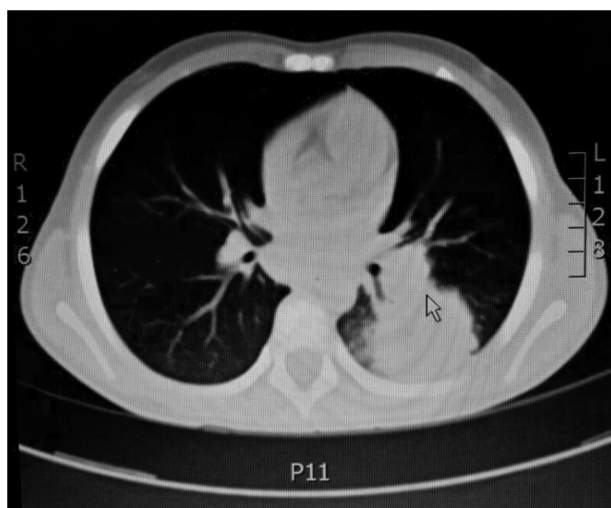
mation dimension 120x100 mm in right lobe of liver. On (CT) scan of the thorax was also revealed cystic formation cca 35 mm in diameter in left basal lung (Figure 1). CT scan of endocranium was normal. Serological test results for echinococcus were negative.

Therefore, according to asymptomatic clinical state of child, it was decided that liver cyst was treated with PAIR method (puncture, aspiration, injection, reaspiration) while lung cyst due to the size was left to treat conservatively with albendazole (15 mg/kg/day) and regular follow up. PAIR confirms the diagnosis and removes parasitic material.

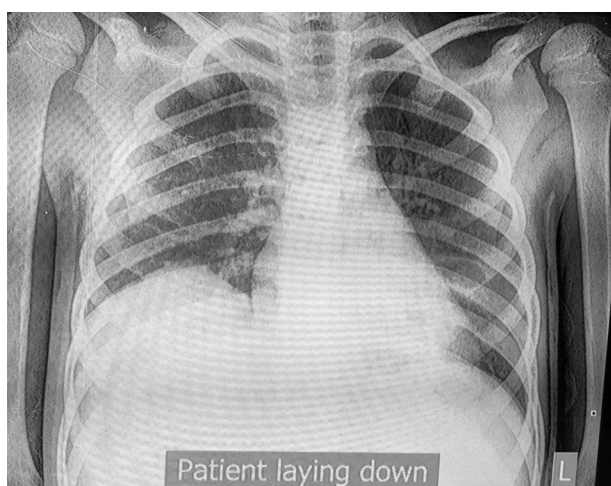
Twelve days after discharge he was admitted to hospital again reporting fever, cough and haemoptysis. His vital signs were as follows: body temperature, 36.8 degrees Celsius; blood pressure, 110/60 mmHg; heart rate, 88/min; and respiratory rate, 20 breaths/min. Pulmonary examinations revealed decreased breath sounds. The rest of physical examinations except herpes labialis and pharyngitis were normal. Laboratory investigation was as follows: elevated Erythrocyte sedimentation ratio (ESR), 116/120, C-Reactive protein (CRP), 188,8 mg/l; with leukocytosis and neutrophilia, elevated IgE 622 IU/ml (normal for age < 200 IU/ml), elevated D dimer 0,8 mg/l (0-0,55 mg/l), flow cytometry showed low number of Natural Killer cells. Serological tests for Echinococcus granulosus were positive (ELISA and IHA). Sputum, bronchoalveolar aspirate and aspirate of cyst were negative for Echinococcus in direct microscopic analysis and cultures while sputum was positive for Candida albicans.

Chest CT scan identified necrotizing pneumonia with progression into pulmonary abscess, 50x60mm, of left basal lung where previously small cyst was described with communication to lobar bronchus (Figure 2), while CT of abdomen showed hepatic cyst in regression. Preexisting echinococcus cyst of left basal lung which is partly evacuated and inflamed could not be excluded as differential diagnosis.

He was treated with a course of broad spectrum antibiotics, antifungal drugs and albendazole as an ant-



**Figure 2.** CT scan shows pulmonary abscess of pre-existing cyst with communication to lobar bronchus



**Figure 3.** Chest X ray after finished treatment

helminthic. Operative evacuation of abscess was performed. His postoperative recovery was uneventful. Chest drain was removed by fourth postoperative day. He was discharge on the seventh day after surgery. Adjunctive chemotherapy with oral albendazole (200 mg twice daily) was administrated for two more weeks total of 4 weeks in second cycles of treatment of hydatid cyst. Chest X ray after finished treatment (Figure 3).

## DISCUSSION

The presented case has a history of asymptomatic-giant liver and small lung hydatid cyst (multivisceral echinococcosis). We consider that the patient was in the phase of secondary hydatidosis even before undergoing the first treatment PAIR method of liver and continued with adjunctive chemotherapy. Our theory is based on the existence of a small pulmonary cyst with fluid and solid tissue partially calcified walls, as it being

known that calcium needs time to accumulate. This case illustrates the extremely complex nature hydatidosis may present, being a rare form of disseminated multivisceral disease with complications (infected hydatid cyst with secondary abscess and potential septic risk).

In study of Arif et al. did though there is not much evidence on the subject, anecdotally, surgeons describe softening and decrease in turgidity of large hydatid cysts with medical therapy (9). According to Sumontra in his article of case report where 29 year woman had surgical treatment of two large lung cysts and continued adjunctive treatment with albendazole of liver cyst, during her recovery and 6 weeks after resection had rupture liver cyst. So given the almost simultaneous change in both cysts, they have postulated that the perioperative antiparasitic therapy for the pulmonary cyst may have been a contributor to the rupture of the large hepatic cysts (10).

*Echinococcus granulosus* involvement in children has a different pattern than adults. In adults, liver is the most common site of localization of the larval forms whilst in children it is more common in the lungs (2). For our case is more important to analyze frequency of combined liver/lung cysts in endemic regions. In study which did Djuricic et al in Serbia during 17 years period identified that involvement of combined liver/lung cysts in patients were 6,0% (11). Authors from Romania revealed that the hepatic localization of the hydatid cyst (50.51%) among children was more common than pulmonary localization (16.49%) and liver and lung localization was found in 22.16% of cases (12). Paredes S et al. in their article of case report and literature review, had conclusion that hepatopulmonary hydatidosis is an unusual entity in children (13). Authors from Serbia Djuricic et al. in their study during period of 1998-2010 found that the number of cases in children continuously decreased over the period (14).

C. Grozavu et al in their study after the analysis of clinical material and studying all 84 cases of multivisceral echinococcosis, from all included locations of the hydatid cysts they have found for our study singificance 22 cases ( 26.19%) as left lung and liver location (3).

Most infected persons are asymptomatic and clinical manifestations vary according to the anatomic location of the cyst (15). The natural progression of untreated cyst may include calcification and death of the cyst, however, more frequently, the cyst gradually enlarges in size (16). Hydatid cyst fluid is highly allergenic and carries a risk of anaphylaxis, thus the intraperitoneal rupture of a hydatid cyst is a life threatening emergency that can be potentially fatal (17).

Medical treatment (chemotherapy) with benzimidazole-like drugs has indication for multivisceral echinococcosis perioperatively or between serial surgeries (18, 19).

According to Grozavu et al. they do not recommend medical treatment as first therapeutic step because it could lead to serious complications, like suppurations with lung parenchyma destruction. Drug therapy has a certain curative effect on cysts smaller than two cm. Their patients did not have any relapses after medical treatment. Conservative methods involve saving the pericyst (residual cavity) after extracting and removing the parasite. These techniques are used for patients with high surgical risk: localization of hydatid cyst is hard to access, patient's comorbidities contraindicates the surgical intervention, etc. PAIR This procedure consists of puncture (P), aspiration (A), injection of parasiticide agent (I), re-aspiration or reinjection (R). It can be applied through percutaneous approach, minimally invasive, or through open surgery.

Surgical treatment of human echinococcosis is based on conservative (salvaging as much tissue or parenchyma as possible) or more aggressive procedures (removing more tissue or parenchyma along with the cyst). First priority is the surgical treatment of complicated cysts (infection, fistula, hemorrhage) no matter their localization. The second priority are uncomplicated cysts with thoracic localization because any general anesthesia can rupture the hydatid cysts with secondary pulmonary infection. Finally, the third priority is the size of the cyst – larger cysts will be removed before smaller cysts (3). Grozavu et al recommend classic surgery with minimal loss of visceral parenchyma. The surgical treatment of multivisceral echinococcosis can be simultaneous (in a single surgical intervention) or successive (separate surgical interventions). Simultaneous attack can be accomplished through a single approach (neighbouring locations) or through separate approaches (distant locations).

Regarding the order of surgical interventions, they have established that it is determined by several priorities, as stated above (3).

Although surgery still remains the most common approach for treatment of CE throughout the world, long-term albendazole therapy has significant efficacy in approximately 70% of cases (21).

A post-treatment follow-up method to prognostically determine the efficacy of treatment should therefore include markers that allow the detection of newly growing or relapsing cysts and the tracking of previously undetected but still viable cysts. Conventional tools used to follow-up cystic echinococcosis patients include imaging techniques such as X-ray, ultrasono-

graphy, computed tomography, and magnetic resonance imaging (22).

## CONCLUSION

Most infected persons are asymptomatic and clinical manifestations vary according to the anatomic location of the cyst, so we want to incindicate the importance of routine ultrasound screening of preschool children, and eventually X ray chest scan.

The aim of this paper was to present a multivisceral echinococcosis and one of its possible complication. The asymptomatic patient was diagnosed to have a liver cyst and left lobe pulmonary cyst. He had undergone PAIR treatment of liver cyst and anti-infective drug treatment and follow-up. We describe complication of hydatid disease where lung cyst had been infected and became life threatening risk of sepsis.

This case report highlights the necessity of being caution with choosing treatment, sometimes even though size of cyst can be irrelevant in making a decision to start the treatment with surgery instead of only medical therapy. This confirms that suggested treatment by Godoku in our case would have been a better option, if we did not choose medical treatment of lung cysts as a first line treatment instead of surgical treatment.

According to the fact that Echinococcosis (hydatidosis) is traditionally endemic in Southeast Europe, Bosnia and Herzegovina included, epidemiological studies of CE, especially pediatric, are rare. Therefore, this article points the need and significance of one large pediatric epidemiological study of CE in Mediterranean region should be done which could have impact on awareness of appropriate treatment with less long term complications.

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Nil.

## CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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## Sažetak

## ISHOD MULTIVISCERALNE EHINOKOKOZE - PRIKAZ SLUČAJA

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**Uvod:** Patogeni agens koji izaziva multivisceralnu ehinokoku je isti kao i onaj koji izaziva ehinokoku jednog organa: *Echinococcus granulosus*. Prema konsenzusu eksperata pod okriljem SZO-NRGE - SZO \_ Neformalna Radna Grupa o Ehinokoku je navela da bi tretman trebalo da bude: (1) perkutani tretman; (2) hirurgija, (3) anti-infektivni lekovi ili (4) pristup gledati i čekati ili kombinaciju navedenih.

**Prikaz slučaja:** Prezentovani slučaj je bio 7-godišnji dečak bele rase, stanovnik ruralnog regiona blizu Tuzle, Bosna i Hercegovina, koji je prethodno imao istoriju asimptomatski uvećane jetre i male hidatidne ciste u plućima (multivisceralna ehinokoku). Smatramo da je pacijent bio u fazi sekundarne hidatidoze čak i pre nego što je podvrgnut prvom tretmanu - PAIR metodi jetre i gde je nastavljeno sa dodatnom hemoterapijom. Dve nedelje nakon otpuštanja iz bolnice, dok je bio na dodatnoj hemoterapiji, imao je jednu od mogućih komplikacija, gde

je došlo do zapaljenja prethodno formirane male hidatidne ciste, na čijem terenu je nastala apscesna masa i potencijalni rizik od sepse, koji je zahtevao hitnu hiruršku intervenciju i antibiotsku terapiju. Operacija i rani postoperativni tok su protekli normalno i pacijent je bio otpušten iz bolnice sa savetom da nastavi sa prethodno započetom dodatnom hemoterapijom (Albendazol) prema protokolu.

**Zaključak:** Većina inficiranih ljudi su asimptomatski i klinička manifestacija može da varira prema anatomskoj lokalizaciji ciste. Stoga, mi želimo da ukazemo na značaj rutinske obrade ultrazvukom u dijagnostici pretškolske dece, kao i eventualnog rentgenskog nalaza. Ovaj prikaz slučaja naglašava značaj odabira adekvatnog tretmana, iako veličina ciste može biti irelevantna pri odlučivanju za operaciju kao prve linije odbrane, umesto konzervativnog lečenja.

**Cljučne reči:** ehinokoku, hidatidna cista, dijagnostika, lečenje.

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## ACUTE COMPLICATIONS IN MULTIPLE MYELOMA

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**Abstract:** Multiple myeloma is a malignant disorder of plasma cells, characterized by uncontrolled and progressive proliferation of a single clone of plasma cells. The disease leads to progressive morbidity and eventual mortality by lowering resistance to infection and causing significant skeletal destruction with bone pain, pathological fractures and hypercalcemia. Improved understanding of the multiple myeloma biology along with the discovery of novel anti-myeloma agents has led to a better-quality treatment of these patients. However, it still remains an incurable disease for the vast majority of patients, with a median survival 2-3 years. Patients with multiple myeloma frequently develop complications that are reason for early mortality within 60 days of diagnosis. Acute complications such as hyperviscosity syndrome, hypercalcemia, spinal cord compression, early infection, bone disease and renal impairment may be life-threatening. The treatment of these medical emergencies has greatly decreased morbidity and early mortality in patients.

**Key words:** multiple myeloma, hyperviscosity syndrome, hypercalcemia, spinal cord compression.

### INTRODUCTION

Multiple myeloma (MM) is a malignant disorder of plasma cells, characterized by uncontrolled and progressive proliferation of a single clone of plasma cells. The disease leads to progressive morbidity and eventual mortality by lowering resistance to infection and causing significant skeletal destruction with bone pain, pathological fractures and hypercalcemia (1). At the time of diagnosis, MM is a heterogeneous disease, with a course that varies on the basis of both disease and host-related factors (age, renal function, stage, chromosomal abnormalities etc.). Multiple myeloma causes significant morbidity and mortality. It accounts for approximately 1% of all malignancies and 13% of hematological cancers. Approximately 50000 patients per

year are diagnosed with MM in EU and US, and 30000 patients per year die due to multiple myeloma (2).

MM can cause many acute complications such as hyperviscosity syndrome, hypercalcemia, spinal cord compression, early infection, bone disease and renal impairment; some of them are life-threatening. The treatment of these medical emergencies has greatly decreased morbidity and early mortality in patients.

### Hyperviscosity syndrome

Hyperviscosity syndrome occurs in cases with high serum paraprotein levels; monoclonal hypergammaglobulinemia is the most common cause, particularly those of IgA or IgG3 type. The reasons for elevated viscosity are increased protein content and large molecular size, abnormal polymerization, and abnormal shape of immunoglobulin molecules (3). Symptomatic hyperviscosity is much more common in Waldenström's macroglobulinemia (10-30%) than it is in myeloma (2-6%). Symptoms of hyperviscosity usually appear when the normal serum viscosity of 1.4 to 1.8 cp reaches 4 to 5 cp, corresponding to a serum immunoglobulin M (IgM) level of at least 3 g/dL, an IgG level of 4 g/dL, and an IgA level of 6 g/dL. Symptoms include bleeding and ocular, neurological and cardiovascular manifestations (mucosal bleeding, blurred vision, headaches, and dyspnea). Immediate therapy of symptomatic hyperviscosity is directed at reduction of blood viscosity by plasmapheresis to control symptoms. Long-term management is directed at control of the underlying disease to prevent production of the monoclonal protein (4).

### Hypercalcemia

Patients with multiple myeloma are commonly diagnosed with hypercalcemia. In fact, hypercalcemia is one of the four diagnostic "CRAB" criteria (calcium ele-

vation, renal insufficiency, anemia and bone disease) used to distinguish smoldering myeloma and monoclonal gammopathies of undetermined significance from active, symptomatic multiple myeloma. About 10 to 15% of patients with multiple myeloma present with hypercalcemia at the time of initial diagnosis, while more than 25% will be found to have hypercalcemia at some point during the trajectory of their disease, usually at the time of disease progression and relapse (5, 6). Hypercalcemia related to multiple myeloma is caused by the breakdown of bone which leads to the release of calcium into the blood (7). This can be a serious problem if appropriate treatment is not given immediately. Symptoms associated with hypercalcemia may be subtle or dramatic, and can include: nausea and vomiting, confusion or depression, myalgia and arthralgia, dry mouth, polydipsia, anorexia, constipation, abdominal pain, and, eventually, coma. An important first step in the treatment of hypercalcemia is to replenish fluids, since hypercalcemia increases filtration across the renal glomerular membrane, interferes with urine concentration, and causes diuresis and hypovolemia. Therefore, aggressive fluid resuscitation is necessary to reverse the hypovolemia and improve urinary calcium excretion. Additionally, diuretics and corticosteroids are often used to treat the hypercalcemia patient. Forced diuresis with loop diuretics can help avoid fluid overload and also increase urinary calcium absorption, and corticosteroids can both decrease calcium absorption from the gut and promote renal excretion. In severe cases and in patients with advanced myeloma-related kidney disease, hemodialysis may be necessary (8). Administration of anti-hypercalcemic medications is the next step. Calcitonin has a rapid onset of action and inhibits bone resorption without the risk of nephrotoxicity, but its ability to decrease calcium is modest and transient. Bisphosphonates (BPs), by contrast, are potent osteoclastic inhibitors with durable activity. These drugs are pyrophosphate analogues in which the central oxygen bridge has been replaced by a carbon that is linked to different side chains. In first generation bisphosphonates, like clodronate, small radicals are linked to the carbon, while in second generation bisphosphonates nitrogen containing moieties, either simple (as in pamidronate) or more complex (as in zoledronic acid) are found (9). Bisphosphonates bind avidly to the bone mineral matrix and therefore accumulate in bone at sites of active bone metabolism. The most common bisphosphonates used for hypercalcemia in myeloma include zoledronic acid (Zometa) or pamidronate (Aredia) (7, 8). Dental procedures, such as root canal or extraction of teeth, may be associated with infection or destruction of the jaw (osteonecrosis), so they should be performed before bisphosphonate treatment is started.

## Spinal cord compression

Skeletal related events are not uncommon in patients with multiple myeloma. Among these, the spine is one of the most commonly involved sites and pathological fractures of the spinal column are the most common spinal involvement of MM (9, 10). Another form of spinal involvement is spinal cord compression. Spinal cord compression is reported to develop in 11-23% of patients with MM. Clinical features depend on the nature of the cord compression, the spinal level, extend of the disease and the rate of development of cord compression and commonly include sensory loss, paresthesiae, limb weakness, walking difficulty and sphincter disturbance (11). Most cord-compression lesions occur due to a pathological fracture of the involved vertebral body or extension of vertebral body myeloma lesion. However, an epidural myeloma could elicit spinal cord compression as a rare form of extra osseous myeloma. This is a very uncommon condition and is found in < 5% of patients with MM (12). Radiographs in patients with an epidural myeloma are usually normal and in some cases, multiple compression fractures and osteopenic appearance of the vertebral body could suggest MM. MRI is the best diagnostic modality for detecting spinal cord compression, epidural masses and marrow involvement of MM. Extraosseous epidural myeloma is believed to originate from lymphoid tissue in the epidural or paraspinal lymph node. In general, extraosseous myeloma involvement at diagnosis or during the course of disease is considered a poor prognosis (9). Failure of neurological recovery has been observed in most reported cases with various treatment modalities (12, 13). No clear guidelines have been established for spinal cord compression caused by a myeloma. Some authors recommend radiotherapy combined with high-dose steroid therapy as the first choice of treatment because MM is highly sensitive to radiotherapy (14). In one report, radiotherapy alone was tried for 63 patients. The authors reported that 76% of the patients experienced an improvement in motor function, 2% deteriorated and local control was achieved in 98% in one year. In contrast, surgical decompression was attempted in several reports and early surgical decompression followed by radiotherapy or chemotherapy was recommended (15). However, the most authors agreed that timely intervention is critical for spinal cord compression by a myeloma. Neurological recovery beyond the critical point is extremely rare regardless of the radiotherapy or surgery attempted. Close observation of the neurological status and patient and medical staff awareness of neurological deterioration are also important to prevent neurological deficits and obtain favorable results. Moreover, the involved level by the epidural myeloma

is one of the important factors to be considered. If the involved level is the cervical or thoracic level, more attentions should be paid to monitor the neurologic status. Surgical intervention prior to non-surgical treatment should be considered in the cases presented with any deterioration of the neurological status (16).

### Early infection

It has been reported that up to 10% of patients with MM die of infective causes early, within 60 days of diagnosis. A variety of factors underlie the increased susceptibility of myeloma patients to infectious disease. The immune factors include hypogammaglobulinemia, impaired lymphocyte function, steroid-related immunosuppression and neutropenia secondary to chemotherapy or marrow infiltration. Physical factors are also important, such as indwelling vascular catheters, impaired mucosal integrity and respiratory compromise because of a combination of pain, vertebral collapse and the use of opiate drugs. The risk of infection is highest in the first 3 months after diagnosis and decreases with response to treatment (17). A recent retrospective analysis of 3107 myeloma patients registered onto UK Medical Research Council (MRC) trials from 1980 to 2002 showed that 10% of patients died within 60 days of trial entry (18) and 45% of these deaths were caused by infection. Blade et al (2001) found in two studies that 7.9% of patients died within 2 months of diagnosis. *Streptococcus pneumoniae*, *Haemophilus influenzae* and *Escherichia coli* are the most frequent causes of infection in myeloma patients (19). Several studies in neutropenic patients suggest that prophylactic antibiotics, such as cotrimoxazole in a small randomized trial in myeloma (20) and levofloxacin in solid tumours (21), may have a role in reducing infection rates but have the potential for leading to antibiotic resistance in the community. Larger studies are required to address the role of prophylactic antibiotics, vaccination strategies and immunoglobulin replacement in multiple myeloma.

### Bone disease

Bone lesions from multiple myeloma are the primary cause of bone pain, which is one of the most common symptoms of multiple myeloma. Bone lesions result in destruction of the bones in myeloma patients and primarily affecting the spine, pelvis or rib cage. In the majority of patients with myeloma, soft spots develop where the bone structure has been damaged. These can extend from the inner bone marrow to the outside surface of the bone. Soft spots appear as "holes" on a standard bone x-ray and are referred to as osteolytic le-

sions. These bone lesions weaken the bone, causing pain and increasing the risk of fractures. Bone loss frequently accompanies multiple myeloma, and 85% of patients diagnosed with multiple myeloma have some degree of bone loss (22). Bone destruction by osteolytic lesions is caused by two separate events. Rapid growth of myeloma cells inhibits normal bone-forming cells, damaging bone. In addition, production of substances that activate the cells that resorb bone, called osteoclasts, is increased. Osteoclasts normally break down old or worn out bone and work with bone-forming cells to repair bone. In the case of multiple myeloma, however, the increased activity of osteoclasts causes bone loss with concomitant loss of bone repair and growth from the suppression of bone formation (23). In patients with multiple myeloma, bone resorption by the osteoclasts is increased and exceeds bone reformation. Calcium lost from the bones appears in increasing amounts in the patient's serum and urine. This increase in bone resorption may result in pain, bone fractures, spinal cord compression, and hypercalcemia. Long bone fractures are treated by immobilization and radiotherapy that can improve pain and promote healing of the fracture site. The recommended dose is 8 Gy for a single fracture. In case of larger lytic lesions of skeleton, an orthopedic surgeon should be consulted and in some patients a surgery with vertebroplasty or kyphoplasty should be done. Bisphosphonates have a favorable effect in controlling the bone lesions in patients with MM, even in those without bone disease at presentation. The duration of the treatment depends on individual factors such as: achieving remission, expressiveness of bone lesions, renal function (24). It is reasonable to stop the treatment in patients who achieve complete response or a very good partial remission and who do not have active bone disease. It is mandatory to perform a good dental inspection always when bisphosphonate therapy is planned and to perform dental procedures such as root canal or extraction of teeth before these agents are started in order to prevent the most difficult complication-osteonecrosis of the jaw.

### Renal failure

Renal failure is a frequent and potentially serious complication that occurs in 20-25% of patients with MM at presentation and in nearly 50% of patients during the disease course. In the majority of cases, renal impairment is caused by the accumulation and precipitation of light chains, which form casts in the distal tubules, resulting in renal obstruction. In addition, myeloma light chains are also directly toxic on proximal renal tubules, further adding to renal dysfunction (25). There are several types of apheresis therapy that

are applicable in MM patients. Plasma exchange (PE) or plasmapheresis involves the separation and removal of the blood cells and other substances from the plasma by centrifugation (based on cell density) or ultrafiltration using large-pore hemofilters (based on molecular size) (26). This method is used to remove pathogenic substances, including paraproteins and inflammatory mediators such as cytokines.

Other factors such as dehydration, hypercalcemia, hyperuricemia, application of nephrotoxic agents for infections, also, contribute to renal failure. Adequate hydration, correction of hypercalcemia and hyperuricemia and antimyeloma therapy should be initiated promptly. For maintenance of a good renal function, patients are advised to stay well-hydrated, to drink enough fluids to produce three liters of urine daily and to avoid nephrotoxic agents including aminoglycosides and non-steroidal anti-inflammatory drugs.

Patients, who have renal failure at presentation, have high level of early fatal outcomes. Supportive care measures are essential and antimyeloma therapy should be initiated as soon as possible. High-dose dexamethasone-based regimens remain the cornerstone in the treatment of these patients, owing to their rapid antimyeloma activity (27). Severe renal impairment and large amount of proteinuria are associated with a lower probability of renal recovery. The addition of novel agents can further increase the rapidity of response and perhaps the probability of restoring renal function.

## CONCLUSION

Despite the discovery of novel anti-myeloma agents, multiple myeloma still remains an incurable di-

sease for the vast majority of patients, with a median survival 2-3 years. The incidence of early death within 60 days of diagnosis is 10% due to many acute complications such as hyperviscosity syndrome, hypercalcemia, spinal cord compression, early infection, bone disease and renal impairment. The most common contributors are bacterial infection (50%) and renal failure (28%) according to the United Kingdom's Medical Research Council (MRC) trials. These complications require specific treatment in addition to therapy directed at the malignant clone that has greatly decreased morbidity and early mortality in patients.

## CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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## Abbreviations

**CRAB** — calcium elevation, renal insufficiency, anemia, bone disease

**IgG** — immunoglobulin G

**IgA** — immunoglobulin A

**IgM** — immunoglobulin M

**MRI** — magnetic resonance imaging

**MM** — myeloma multiplex

**PE** — plasma exchange

**UK MRC** — United Kingdom's Medical Research Council

## Sažetak

# AKUTNE KOMPLIKACIJE MULTIPLOG MIJELOMA

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Multipli mijelom je maligno oboljenje plazma ćelija, koje karakteriše nekontrolisana i progresivna proliferacija jednog klon plazma ćelije. Oboljenje vodi do progresivnog morbiditeta i eventualnog mortaliteta, tako što snižava otpor organizma na infekcije i dovodi do značajnih oštećenja na skeletu, praćenog bolom u kostima, patološkim frakturama i hiperkalcemijom. Bolje razumevanje biologije multiplog mijeloma zajedno sa otkrićem novih anti-mijelomskih agenasa dovelo je do boljeg lečenja bolesnika. Međutim, multipli mijelom je još uvek neizlečiva bolest za većinu pacijenata, sa sred-

njom stopom preživljavanja 2-3 godine. Pacijenti koji boluju od multiplog mijeloma često razvijaju komplikacije, koje su razlog njihovog ranijeg mortaliteta u okviru prvih 60 dana od postavljanja dijagnoze. Akutne komplikacije kao što su hiperviskozni sindrom, hiperkalcemija, kompresija kičmene moždine, rana infekcija, oboljenja kostiju i bubrega mogu biti životno ugrožavajuća. Lečenje ovih urgentnih medicinskih stanja uveliko smanjuje morbiditet i rani mortalitet kod ovih bolesnika.

**KLjučne reči:** multipli mijelom, hiperviskozni sindrom, hiperkalcemija, kompresija kičmene moždine.

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## THE ROLE OF REGIONAL CENTERS AND UNIVERSITY CHILDREN'S HOSPITAL IN DEVELOPMENT OF HOME MECHANICAL VENTILATION NETWORK

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**Abstract:** Application of home mechanical ventilators represents the future in the treatment of children with chronic respiratory insufficiency. In this way patients are treated in the home environment, they have full support from their families, they are protected against nosocomial infections and their condition is monitored by medical staff. The role of regional centers is very important in the future development of the home mechanical ventilation network. Doctors in these centers under the full support of the University Children's Hospital physicians can assist and monitor the treatment of children on the household respirators.

**Key words:** home mechanical ventilation, family support, children.

### INTRODUCTION AND CONTEXT

Children who need home ventilation represent the group of patients with special needs. There is no unified program for the treatment of these children in our country and there is no home ventilation network. Also there is no guide that applies to all segments of the treatment of these complex patients.

Use of home mechanical ventilators has started for more than twenty years ago in the rest of the world. Highly developed countries have the most experience in using this form of chronic respiratory therapy. Based on five years of experience, from 2011 to 2015, in treating children with chronic respiratory failure in the neonatal and pediatric intensive care unit at the University Children's Hospital, it was concluded that the development of a network of home mechanical ventilation and home care for these patients would be the best approach for solving the problem. American Thoracic Society a few years ago formed an expert interdisciplinary team as a working group, which developed home ventilation network for children with chronic respira-

tory failure (1, 2). The main issues were finding the best way to treat these children, organize the network, include patient's family members, evaluate their treatment and finally make clear guidelines and recommendations for the treatment.

The analysis of data from the University Children's Hospital, Department of Pediatric and Neonatal Intensive Care, for the period from 2011 to 2015, showed that we had 68 patients who required prolonged mechanical ventilation for more than 30 days. The total number of days of mechanical ventilation for these patients was 3491 days or 83784 hours of mechanical ventilation. Minimum duration of the mechanical ventilation was 30 days and the longest 180 days. Average number of days of mechanical ventilation per patient was 51.4, or 1,233.6 hours. The longest duration of mechanical ventilation was 698 days. These data are not related to neurosurgical patients who are being treated at the department of surgical intensive therapy. In the period of five years, from these 68 patients 21 of them had indication for home mechanical ventilation, from which only 9 went on home mechanical ventilation therapy. The others remained hospitalized in our institution or in the regional centers that have ventilators. Why is that so?

Current procurement procedures for getting home ventilators relate to ventilator for non-invasive ventilation (NIV) which is being approved by the Commission of the Health Insurance Fund. This kind of ventilators can insured for patients suffering from severe forms of muscular dystrophy (Duchenne), spinal muscular atrophy, amyotrophic lateral sclerosis (ALS), high lesions of the cervical spine. Procedure for getting the ventilator for home use has few steps. First they need to have an opinion from neurologist and pulmonologist or pneumophthysiologist, then opinion from the

Commission for non-invasive ventilation and finally from medical commission who gives permission for getting the ventilator. In this way patients can get only ventilator for non-invasive ventilation (3).

If the patient needs ventilator for invasive mechanical ventilation, parents have to buy it. But they also need aspirator, tubes for suction, pulse oxymeter etc. Parents must be trained to handle the ventilator, and service, in case of any failure of the ventilator has to be available. It is also necessary to provide specialized nurse, physiotherapist, nutritionist, psychologist and social worker. Doctors from the primary health care have very important role in this network as they have to monitor the patient's condition all the time. In addition, it is necessary to make notes about patient's medical condition every day (4).

This multidisciplinary approach is necessary for the successful treatment. Based on the data from literature, this form of treatment has many advantages over the long term hospitalization. Comparing the costs of mechanical ventilation (hospital costs of average \$21,570 per month, per patient and costs of home treatment of average \$7,050) show that the savings are around \$14,520. Other benefits are improving the quality of life of the patient and family, better socialization; pediatric patients can be with their parents all the time which is very important for their psychological state. Home mechanical ventilation is reducing hospital infections and enables intensive care units to have higher capacity for the treatment of acute patients (1, 4).

On the basis of existing guidelines, the indications for mechanical ventilation at home are very clear (Table 1) (1). There are also clinical protocols that relate to training for parents as well as doctors from primary health care, who represent a very important factor in the treatment of these patients.

Standardization of procedures, with the support of the Ministry of Health of the Republic Serbia and Health Insurance Fund, who has to invest in this type of treatment, is done by a team of experts who need to make guidelines for the treatment of these patients and training program for their parents and all members of medical team involved in using home mechanical ventilators.

**Table 1.** Indications for mechanical ventilation in pediatric patients at home

| Indications                                                                                                                    |
|--------------------------------------------------------------------------------------------------------------------------------|
| Increased Respiratory Load                                                                                                     |
| Bronchopulmonary dysplasia<br>Hypoxia and hypercapnia<br>COPD<br>Restrictive parenchymal lung diseases                         |
| Ventilatory Muscle Weakness                                                                                                    |
| Motor neuron diseases<br>Primary myopathies<br>Spinal cord injury                                                              |
| Failure of Neurological Control of Ventilation                                                                                 |
| Congenital central hypoventilation syndrome<br>Myelomeningocele<br>Acquired central hypoventilation syndrome (brain tumor etc) |

With the future development of telecommunication and telemedicine, these patients could be handled much easier and that would be a great benefit for patient's mental health as well as for their family members (5).

## CONCLUSION

In order to make adequate organization of home mechanical ventilation network, it is necessary to do a feasibility study, study of quality of life of these patients and also a cost benefit of this treatment. Guidelines, based on good clinical practice, are very important for the implementation of home mechanical ventilation.

## Conflict of Interest

The author declares no conflict of interest.

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## Sažetak

# ULOGA REGIONALNIH CENTARA I UNIVERZITETSKE DEČIJE BOLNICE U RAZVOJU MREŽE KUĆNE MEHANIČKE VENTILACIJE

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Primena kućnih mehaničkih ventilatora predstavlja budućnost lečenja dece sa hroničnom respiratornom in-

suficijencijom. Na ovaj način se pacijenti leče u kućnom okruženju, imaju punu podršku porodice, zaštićeni su od

nozokomijalnih infekcija i njihovo stanje se prati od strane medicinskog osoblja. Uloga regionalnih centara je veoma značajna u budućem razvoju mreže kućne mehaničke ventilacije. Lekari u ovim centrima, uz punu podr-

šku lekara Univerzitetske Dečije Bolnice, mogu asistirati i pratiti lečenje dece koja su na kućnim respiratorima.

**Ključne reči:** kućna mehanička ventilacija, porodična podrška, deca.

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2. **Knjiga:**

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The journal is published in English, with the summary translated into Serbian.

### GENERAL GUIDELINES

Text of the paper should be typed in a word processing program *Word*, written in Latin, double-spaced, only in *Times New Roman* font size 12 points. All margins should be set at 25 mm, and the text should be typed with the left alignment and paragraph indentations of 10 mm, without dividing the words.

The manuscript should be arranged as following: title page, abstract, key words, introduction, patients and methods/material and methods, results, discussion, conclusion, references, tables, figure legends and figures.

Each manuscript component (title page, etc.) begins on a separate page. All pages are numbered consecutively beginning with the title page.

References in the text are designated with Arabic numerals in parentheses, and the order in which they appear in the text.

**Manuscript volume.** The complete manuscript, which includes title page, short abstract, text of the ar-

ticle, literature, all figures and permissions for them and legends (tables, images, graphs, diagrams, drawings), title page and abstract in English, can have the length up to 5000 words for original paper, report, paper on the history of medicine and literature overview, while for patient presentation, practice paper, educative article it can be up to 3000 words, and other papers can be up to 1500 words.

The word count check in a document can be done in *Word* processor program in submenu *Tools Word Count* or *File Properties Statistics*.

All measurements, except blood pressure, are reported in the System International (SI) and, if necessary, in conventional units (in parentheses). Generic names are used for drugs. Brand names may be inserted in parentheses.

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A short title of less than 50 spaces, for use as a running head, is included.

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A list of abbreviations used in the paper, if any, is included. List abbreviations alphabetically followed by an explanation of what they stand for. In general, the use of abbreviations is discouraged unless they are essential for improving the readability of the text.

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Original work should have the following headings: introduction, aim, methods, results, discussion, conclusion, references.

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Review of the literature include: an introduction, subheadings, conclusion, references.

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Spates ST, Mellette JR, Fitzpatrick J. Metastatic basal cell carcinoma. *J Dermatol Surg.* 2003; 29(2): 650–652.

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For any further instructions and information, contact Editorial Board.

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