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Original Article

Evaluation of Quality of Life after Implantation of Light or Standard Polypropylene Hernia Meshes

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Abstract

Introduction: The present pilot study evaluates the quality of life of Bulgarian patients after a conventional hernia operation in which light or standard polypropylene hernia meshes were used.

Materials and methods: Sixty-eight patients planned for recovery of primary or recurrent open hernia with implanted standard or lightweight polypropylene meshes were included in the study. Patients' data were collected prospectively for a 5-month period (October 2017 - February 2018) on the basis of the case histories. The patients were interviewed using the EQ5D questionnaire and a visual analogue scale. Follow-up of each patient's results was performed up to a year after surgery.

Results: Three months after the operation, the patients reported only the presence of pain. On average, 24.5% of patients experienced mild pain and 20.3% - severe pain. In the standard mesh group, on average, the mild pain was 7.69%, swelling 3.84%, and foreign body sensation - 15.38% one year after the surgery. In the light mesh group the reported mild pain was 6.69%, pulling without pain - 13.33%, and foreign body sensation - 6.69%. There was no statistically significant difference in the pain level according to the used mesh, but in the group with implanted standard meshes, the reported problems prevailed. At the end of the survey period, the average score was 84.39±13.67.

Conclusions: Hernia operation reduces pain 1 year after the procedure. The intensity of chronic pain one year after the surgery is relatively similar for both light and standard meshes in conventional inguinal hernia repair. The differences in the overall quality of life are insignificant in the long run. An individualized choice, based on the patients' characteristics and safety of meshes, should be done by the healthcare specialists.

PENSOFT.

INTRODUCTION

Transplantation of medical devices affects the general well-being of individuals. Evaluation of the quality of life of such patients is a common practice. It can help to control symptoms and to improve treatment impact on the patient's health status.[1]

The most commonly performed hernia repair is the open inguinal hernia repair. After such a repair, the operative procedure, the mesh or the mesh-induced scar tissue may cause chronic pain. The studies found in the literature examined the quality of life in inguinal hernia in terms of the techniques used, the immediate postoperative pain, and the length of the full recovery period.[2-4]

The quality of life of patients with implanted different standard or light meshes has been assessed usually by the Short Form multipurpose health survey questionnaire (SF 36), a standardised measure of health-related quality of life developed by the EuroQol Group - EQ5D or visual analogue scale (VAS) 6 months to one year after operation and the main conclusion was that quality of life is improved significantly after 6 months compared with the preoperative assessment. There were no differences between the treatment groups. A tendency for a faster return to normal life when light meshes in bilateral hernias were used has been reported.[2,5]

Because of the huge number of investigations focusing on the hernia meshes outcomes, the best approach is to explore the published meta-analyses or systematic reviews on the problem. Systematic reviews and meta-analyses summarizing the literature until 2012 have already demonstrated the benefits of light weight meshes (LWM) on chronic pain and the feeling of a foreign body.[6,7] Sajid et al.[6] analysed the results of nine randomized control trials (RCT) including 2310 patients. The main conclusion was that the use of LWM for open inguinal hernia repair reduced the incidence of chronic groin pain.[6]

Smietanski et al. also used meta-analyses to assess the recurrence rate, several aspects of chronic pain, and foreign body feeling 6-60 months post operation.[7] The authors identified eight prospective RCTs. Analysis showed that there was no significant difference regarding the recurrence (odds ratio 1.11; 95% CI, 0.57–2.14; *p*=0.77) or severe pain (odds ratio 0.99; 95% CI, 0.48–2.02; *p*=0.97). They stated that lightweight meshes could be considered a material of choice in primary inguinal hernioplasty.[7]

The last detailed systematic review on available randomized control trials for the outcomes of recurrences, chronic pain, and a feeling of a foreign body in case of using of LWM or heavyweight mesh (HWM) in open inguinal hernia repair was published by Bakker.[8] The RCTs that compared lightweight (<50 g/m^2) and heavyweight (>70 g/m^2) meshes in patients undergoing open inguinal hernia repair using the same operative technique (Liechtenstein) were included in the review. The outcome parameters were chronic pain and/or recurrences and a follow-up period of at least 3 months. All 4576 patients were included in the systematic review - the LWM group contained 2257 patients and the HWM group included 2319 patients. No statistically significant difference between lightweight mesh and heavyweight mesh was found for the recurrence rates or severe pain.[8]

The measure of hernia operation success in Bulgaria is still the recurrence rate and studies describing the quality of life of patients are few. There are some articles on the quality of life of patients from leading clinical centres in the country.[9-11] The available studies on the subject differ in terms of type of hernia (inguinal or ventral hernia), the operative technique (laparoscopic and conventional operation), the rating scale (SF-36, Eura HS-QoL), and the duration of the follow-up (four, six, 12 postoperative weeks, and one year after surgery).[9-11] The studies found that the quality of life of patients was high and patients with implanted meshes had a higher quality of life than those patients operated without meshes.[9] Significantly worse results were reported in conventionally operated patients. Three months after surgery, the difference in the reported pain disappears but persists poorer results in terms of physical limitations and discomfort after conventional hernioplasty.[11]

The quality of life after implantation of different meshes in conventional open hernioplasty in Bulgaria is not well studied and the published results are insufficient so that we can apply pharmaco-economic analyses. This fact attracted our attention to monitor the extent to which early postoperative pain depends on the type of used meshes.

AIM

The aim of this study was to investigate whether the severe postoperative pain persists for one year after surgery in case of conventional open hernia operation and to calculate quality-adjusted life years (QALY) of the Bulgarian patients for the purposes of decision making in the healthcare settings.

MATERIAL AND METHODS

Participants

The study included 68 patients operated for inguinal and ventral hernia in two hospitals in Bulgaria. Light or standard polypropylene hernia meshes (TiO$_2$, Parietene, Surgimesh, Microval-PP, and Surgipro) were implanted. The number of implanted standard meshes was 43 (group SWM) and the number of light meshes – 24 (group LWM), while one patient was operated without a mesh. Patients' data were collected prospectively for a 5-month period (October 2017 - February 2018) on the basis of case histories. For each patient, gender, age, treatment method, mesh used, complications/reoperations, and pain assessment were described. We defined postoperative pain as pain at the operation site, in the absence of recurrence, inflammatory complications or liquid contents around the implanted

prosthesis. Patients fulfilled the informed consent to participate at the analysis. The ethical committees of Medical University of Sofia approved the study.

Data analyses

The operated patients were interviewed using the EQ5D questionnaire. The EQ5D rating scale on day 1, 3 months, and one year after the operation was used to assess the quality of life. The quality of life is based on the sum of five dimensions, distributed in the following areas: physical activity, self-care, normal activities, pain/discomfort, and depression. Each of the questions has three dimensions that grade the patient's condition. The first answer (A) indicates no problems, the second answer (B) - the presence of any problems, and the third answer (C) - severe problems.

Each answer from the questionnaire was indexed with a coefficient of health utility in accordance with the methodology of Drummond.[12] We measured the outcomes of health interventions in terms of QALYs which are practical instruments for assessing the impact of health procedure on the patients' quality of life.[12] The QALYs lived by an individual in one year are calculated multiplying the health-related quality of life weight for the relevant year of life. The mean QALY for the groups operated with light and standard meshes was calculated and compared.

$$QALY = V(Q) \times Y \qquad (1)$$

where QALY is the notation for health condition, Y – years, V(Q) – utility index

The number of patients interviewed one day after the operation was 15 versus 19 patients with implanted light and standard meshes, respectively. The number of surveyed patients after three months was 18 in the SWM group, compared to 12 patients in the LWM group. The effect of the meshes after one year was assessed and 26 patients with implanted heavy meshes and 15 with implanted light meshes were interviewed.

The patients were also asked to self-assess their health status after surgery using 100-points visual analogue scale (VAS). Zero points indicated the worst possible condition and 100 points - the best possible condition imagined by the patient. The patients' condition was reported on days 1, 90, and one year after the surgery. The patients were interviewed by a telephone call to follow up complaints related to the performed surgical intervention during the described time intervals.

The questionnaires corresponding to patient's health status were analysed and summarised by descriptive analysis, graphical analysis, comparison of relative shares, tests of Kolmogorov-Smirnov and Man-Whitney, as well as Student's *t*-test. The statistical analysis was performed using the MedCalc Statistical Software version 17.9.7. Differences in the values of the parameters were considered statistically significant at *p*<0.05.

RESULTS

Demographic characteristics

The surveyed patients were 13-86 years old, with a mean age 63.08±12.84 yrs. The mean age of men was 62.86±13.51 yrs and the mean age of women was 63.3±12.18 years.

Groin and ventral hernia were operated on and only one patient did not describe the type of hernia. The time between the first symptoms and the diagnosis was between 2 weeks and 10 years, with 86% diagnosed within 1 year. The shortest period of surgery after the first symptoms was one day, and the longest - 23 years. 82.14% of patients were operated on within one year after diagnosis. The used hernial meshes were Parietene - 10.29%, TiO_2 - 35.29%, Surgimesh - 7.35%, Microval - PP - 20.59%, Surgipro - 5.88%, other meshes - 7.35%. Eight people did not indicate the brand of the meshes used but they were standard and one patient was operated without a mesh.

The reported reoperations concerning adult patients with problematic connective tissue: the established number of reoperations was between 1 and 4. A third operation was performed in two patients (2.94%). In four of the patients, the first operation was performed more than 50 years ago and was without meshes (5.88%) **(Table 1)**.

Evaluation of QALY

The results of patients' quality of life with implanted light and standard meshes one day after the operation are presented in **Figs 1A, 1B**. 31.75% of patients with implanted standard meshes and 6.66% of the patients after implantation of light meshes had serious problems with walking, self-care, and normal activities. The assessment of the severity of pain showed that the prevalence of moderate pain in the SWM group was 73.68% versus 66.67% in the LWM group, while the results for severe pain were similar - 5.26% in the SWM group compared to 6.67% in the LWM group. The results showed that 73% in both groups were not depressed and 20% were slightly depressed. Only between 5% and 6.67% of patients were very depressed because of the surgery procedure **(Figs 1A, 1B)**. Statistical analysis of data showed that the existing differences in the results were not statistically significant (*p*<0.05).

After three months, the patients did not report any problems related to their physical activity, self-care, and normal activities. Only the level of pain was assessed **(Fig. 2)**.
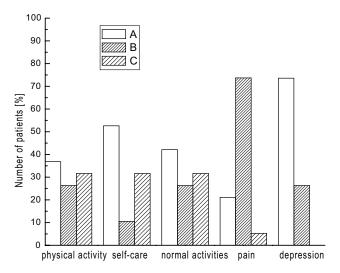
Fifty-three percent of patients with implanted standard meshes versus 58% of the patients with light meshes did not experience pain, or an average of 55.5% of patients felt no pain. On average, 24.5% of patients experienced mild pain (24% vs. 25% for light meshes) and 20.3% reported severe pain (23.53% in the SWM group and 16.6% in the LWM group). There was no statistically significant difference in the results, but in the group with implanted standard meshes, the number of patients experiencing severe pain was 7%

Table 1. Demographics and clinical characteristic of patients

Category	Sub-group	Number/distribution (%)
Age	Over 51 yrs	53 (77.94%)
Mean age		63.08±12.84 yrs
Gender	Male	52 (75%)
	Female	16 (25%)
Type of hernia	Groin hernia	51 (75%)
	Ventral hernia	16 (23.25%)
Time of operation after diagnosis	Up to 1 month	53.57%
	Between 1 month and 1 year	28.57%
Used meshes	Standard meshes	63.45%
	Light meshes	35.3%
Complications	Reoperations	14 (20.59%)

Figure 1A. Results for patient's status one day after operation when standard meshes were implanted (**A** - no pain, **B** - moderate pain, **C** - severe pain).

Figure 1B. Results for patient's status one day after operation when light meshes were implanted.

higher (**Fig. 2**).

The effect of meshes one year after surgery was assessed. Pain, swelling, and foreign body sensation were compared. 26.92% of the patients with implanted standard meshes reported problems - mild pain (7.69%), swelling (3.84%), and foreign body sensation - 15.38%. The same proportion was obtained in the group with implanted light meshes - 26.67% from the patients with implanted light meshes reported problems that included mild pain (6.69%), pulling without pain (13.33%), and foreign body sensation - 6.69% and one reoperation (**Fig. 3**).

The physical status of the patients according to their age was self-assessed. They were divided into six age groups with the time interval of 10 years. Only the groups of patients over the age of 50 was considered, due to the small number of patients in the groups up to 50 years - between 1 and 2 patients. During the first day, the self-assessment
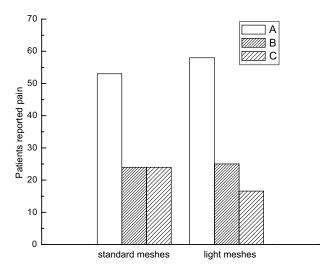

Figure 2. Results for patients' status three months after operation. **A** - no pain, **B** - moderate pain, **C** - severe pain.
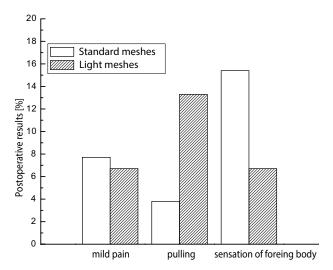
Figure 3. Postoperative results after a one-year period.

Figure 5. Calculated utility index after 1 day, three months, and one year after operation.

scores were in the range of 60-75 points **(Fig. 4)**. In the subsequent recovery period, the scores gradually increased in all age groups. After three months, the mean scores in all groups were over 75 points, with the highest score in the group of 60-80 years old patients **(Fig. 4)**. The average values of the points increased on average by 10 units for the reported period - from 63.58±2.54 after 1 day, to 72.24±13.52 after 3 months. At the end of the study period (one year), the average number of points of all patients was 84.39±13.67, which shows that they rated their health status as very good.

The calculated utility indices for the three periods are presented in **Fig. 5**. The utility index for both groups increased from 0.536 to 0.884 for standard meshes and from 0.66 to 0.904 for light meshes **(Fig. 5)**.

QALY was calculated and the mean values for both groups were compared.[13] The acquired QALY for one year was higher for light meshes - 0.858 compared to standard meshes - 0.808.
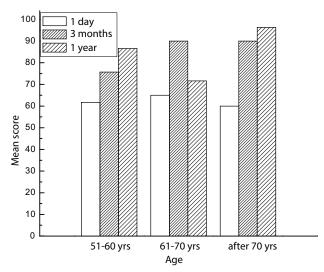

Figure 4. Self-assessment of the physical status of patients according to their age one day, three months, and one year after operation.
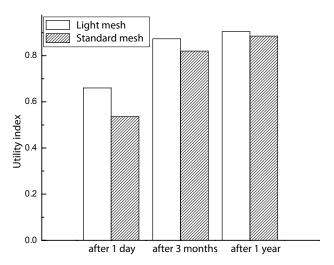
DISCUSSION

The most common complaints in the postoperative period of patients undergoing hernia surgery are pain in the area of surgery. Long-term follow-up of each patient's quality of life assessed by QALY and VAS showed that the tendency was for complaints reduction in the first 12 months after the surgical procedure.

The calculated utility index (0.884-0.904) is comparable to that obtained by G. Sgourakis (0.946).[14] Sharma et al.[15] work with the following utility indexes in inguinal hernia surgeries which are used in the patient health model. One week after the operation, the utility index is 0.68±0.24, 3 months after surgery in the recovery period, the utility index is 0.86±0.2, and in the presence of complications, the utility index is 0.836±0.021.[15] Utility weights used were adjusted by the UK population norms for males and are age adjusted.[16,17]

The results reported by Schouten et al.[18] and Welty et al.[19] suggested that the presence of pain was generally about two times weaker in the group with implanted light meshes but this statement was not confirmed. The monitored intensity of the pain during the period showed that the percentage of patients who did not experience pain after three months decreased by about 30%. From 78.8% compared to 73.5% experiencing pain on the first day, the ratio was 52% to 60.6% after a month and between 7%-8% of patients complained of pain at the end of the year. The intensity of pain after surgery is relatively similar, with no statistically significant difference depending on the meshes used.

Post et al.[2] compares the quality of life in patients with implanted different meshes while one type of operation was applied. The use of a lightweight mesh is associated with significantly less pain during exercise after 6 months (*p*=0.042). Fewer patients reported a foreign body sensation after implantation of light mesh (17.2% vs. 43.8% with heavy mesh; *p*=0.003). The quality of life improved sig-

nificantly after 6 months compared with the preoperative assessment and there were no differences between the treatment groups.[2]

We compared the data on the presence of pain and foreign body sensation in the area of the operation 3 months and 1 year after the operation with the results used by Sharma et al.[15] The researchers reported that 29.3% of patients complained of pain 3 months after surgery and 12.9% - 1 year after surgery. The sensation of a foreign body subsides more slowly - up to one year after surgery, 50.09% report such a problem, and after five years, these patients decrease to 9.5%.[15] Three months and one year after the operation, our results are comparable with those of Sharma et al.: 24% versus 29%, and 7-8% versus 12%. The sensation of a foreign body is close after 5 years.[15]

Köckerling and Simons[4] examined the quality of life in inguinal hernia in terms of the techniques used. They use the SF 36 questionnaire to assess the quality of life in unilateral inguinal hernias in conventional operations using two different methods - preperitoneal access and the Liechtenstein method. The health status of the groups was assessed with the same number of points 81.5 compared to 82.5. The pain was higher in open surgery with preperitoneal access (91.6 points compared to 82.5 points) in the Liechtenstein method.[4] The scores reported by Köckerling and Simons are consistent with the results we obtained (84.39±13.67). We compared the results obtained on the quality of life with data from other clinical centres in the country.[9-11] The available Bulgarian studies on the subject differ in terms of the type of hernia, the operative technique, and of the duration of follow-up, only qualitative comparisons of the results were made. The mean age 63.08±12.84 is close to the reported mean age in the literature (66.7–69.3 years) as usually 73.8% of patients are over 50 years, which corresponds to the age characteristics of our respondents - 77.93% are over 50 years.[4,8] The reported reoperations are 20.59%, which is consistent with data on recurrences of 25-30% published by Arnaudov et al.[20]

Usually the standard meshes (Parietene, Surgimesh, Microval, and Surgipro) were implanted. There was no change in the use of standard or heavy meshes compared to the results reported for 2018, when we found that 51.45% of implanted meshes were heavy, compared to 50.5% in 2015, but the use of light meshes has increased up to 35.29%.[21]

In light meshes, one reoperation was reported. The implantation of light meshes is characterized with pulling without pain (13.3%) while implantation of standard meshes with foreign body sensation (15.38%). After the first three postoperative months, the pain decreases and the differences in quality of life are insignificant in the long run. Patients' quality of life depends on the used meshes, but this trend decreases one year after surgery. At the end of the study period, patients rated their condition as 'very good'. The study shows that the health culture of the population is improving - 86% of patients are diagnosed within 1 year, 53.57% of patients are operated within 1 month after diagnosis, and 82.14% within one year after diagnosis. It still prevails up to one year after diagnosis. The use of standard and heavy meshes is still prevalent, but the use of light meshes has increased. Heavy meshes are mainly used in the district hospitals, while light meshes in the leading clinical centres, most of which are monofilament.[21]

Limitations of the study

The main limitation of the study is the small number of patients included in the investigation. Lightweight mesh improves functional outcome in conventional inguinal hernia repair but the absence of statistically significant difference in terms of quality of life did not provide a strong, evidence-based recommendation on the use of light meshes.

A nationally representative survey needs to be conducted with a sufficient number of participants to assess the quality of life of patients undergoing hernia surgery in the country.

CONCLUSIONS

Hernia operation leads to pain reduction 1 year after the procedure which is relatively similar between both light and standard meshes in conventional inguinal hernia repair without differences in the overall quality of life. An individualized choice, based on the patients' characteristics and safety of meshes, should be done by the healthcare specialists.

Acknowledgements

Conflict of Interest

The authors declare that they have no conflict of interest.

Author contributions

G.P. and M.D.: conception and design; G.P.: administrative support; N.G. and S.S.: provision of study materials or patients; N.G. and M.D.: collection and assembly of data; M.D. and G.P.: data analysis and interpretation; M.D., M.K., and G.P.: manuscript writing; all authors: final approval of manuscript.

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Оценка качества жизни после имплантации облегчённых и стандартных полипропиленовых грыжевых сеток

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Резюме

Введение: Настоящее пилотное исследование оценивает качество жизни болгарских пациентов после традиционной операции по удалению грыжи, в которой использовались облегчённые или стандартные полипропиленовые грыжевые сетки.

Материалы и методы: В исследование включены 68 пациентов, которым планировалось восстановление первичной или рецидивной открытой грыжи с имплантацией стандартных или облегчённых полипропиленовых сеток. Данные пациентов были собраны проспективно за 5-месячный период (октябрь 2017 г. – февраль 2018 г.) на основе историй болезни. Пациенты были опрошены с использованием опросника EQ5D и визуальной аналоговой шкалы. Последующее наблюдение за результатами каждого пациента проводилось в течение года после операции.

Результаты: Через три месяца после операции пациенты отмечали только наличие болевого синдрома. В среднем 24.5% больных испытывали слабую боль и 20.3% – сильную боль. В группе со стандартной сеткой через год после операции в среднем лёгкая боль составила 7.69%, отёк 3.84%, ощущение инородного тела 15.38%. В группе с облегчённой сеткой сообщалось о слабой боли в 6.69%, безболезненном натягивании – в 13.33% и ощущении инородного тела – в 6.69%. Статистически значимой разницы в уровне боли в зависимости от используемой сетки не было, но в группе с имплантированными стандартными сетками отмеченные проблемы преобладали. В конце периода обследования средний балл составил 84.39±13.67.

Заключение: Операция по удалению грыжи уменьшает боль через 1 год после операции. Интенсивность хронической боли через год после операции относительно одинакова как для облегчённых, так и для стандартных сеток при традиционной пластике паховой грыжи. Различия в общем качестве жизни в долгосрочной перспективе незначительны. Индивидуальный выбор, основанный на характеристиках пациентов и безопасности сеток, должен осуществляться специалистами здравоохранения.

Ключевые слова

EQ5D, операция по удалению грыжи, уменьшение боли, QALY

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