

Surgical Treatment Efficiency Of Patients With Scar Strictures In Extrahepatic Ducts Using Superelastic Titanium Nickelide Constructions

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Abstract

Over the past few decades, there have been significant changes in the prevention, diagnosis and treatment of many complications of abdominal surgery, including cicatricle strictures of the extrahepatic ducts, thanks to constantly evolving medical technologies. Nevertheless, the treatment of cicatricle strictures in extrahepatic bile ducts remains as difficult task that requires great experience and skill of surgeon. Introduction of superelastic titanium nickelide structures with a memory effect was another step in the development of reconstructive hepatobiliary surgery. This work aims to identify the effectiveness of surgical treatment of patients with cicatricle strictures of the extrahepatic ducts using superelastic titanium nickelide structures. Materials and methods: a retrospective analysis of the case histories of 81 patients with cicatricial strictures of the extrahepatic bile ducts was carried out. Depending on the method of surgical intervention, all patients were divided into 2 clinical groups depending on the method of surgical treatment. Long-term results of surgical treatment in the form of quality of life were assessed using MOS SF - 36 (Medical Outcomes Study Short Form 36) and GSRS (Gastrointestinal Symptom Rating Scale) upon patient admission to the hospital, 1, 3, 6, 12 months after surgery and in long-term periods (from 2 to 7 years). Statistical processing of the material was carried out using Excel 7.0 for Windows XP, Statistika for Windows 6.0. The significance of differences in mean values was determined based on Student's t-criteria. Results: on all SF-36 scales, the comparison group showed a significant decrease in the quality of life compared to the main group ($p < 0.001$). In patients of the main group, physical and mental components of health are higher than in patients of comparison group. In patients of the comparison group, in the long-term period, GSRS indicators (especially abdominal pain syndrome, reflux syndrome, dyspeptic syndrome) in total significantly ($p < 0.05$) have higher values compared to the main group. And according to the scales of constipation syndrome and diarrheal syndrome, the differences are not significant ($p > 0.05$). Conclusions: in patients of the main group, who received titanium nickelide stents, in the long-term period, the life quality is higher than in patients of the comparison group operated on by traditional methods (according to the general SF-36 and specific GSRS questionnaires).

Keywords: Cicatricle strictures of extrahepatic ducts; titanium nickelide implants; titanium nickelide stents; late postoperative period; quality of life.

INTRODUCTION

Among the early intra-abdominal complications after various types of cholecystectomy, one of the leading places is occupied by strictures of the extrahepatic bile ducts (CSEBD) [Vishnevsky *et al*, 2017; Ivanov *et al*, 2018; Tokarenko, 2014; Kim *et al*, 2014]. Surgical interventions for this pathology are for the most part very complex, and their results do not always satisfy surgeons and patients. CSEBD after repeated operations on the biliary tract develop long term in 20-30% of patients, and mortality reaches 8-40% [Semenov *et al*, 2021].

Damage found during cholecystectomy should be repaired immediately. Bile duct injuries detected in the postoperative period require an interdisciplinary approach, and an algorithm for the treatment of each type of lesion should be proposed [Dambaev *et al*, 2007; Janssen *et al*, 2014]. This reduces the incidence of postoperative complications and prevents the development of CSEBD in the early postoperative period [Doskhanov *et al*, 2021].

While the long-term impact on patients is associated with a significant reduction in quality of life, loss of productivity, and high rates of disability, definitive reconstructive surgery remains the main treatment for extrahepatic bile duct strictures. However, even in experienced biliary surgeons, the incidence of strictures after reconstructive surgery can still be as high as 10-20%. Only 1/3-1/2 CSEBD can be diagnosed in time, more than 70% of extrahepatic bile duct strictures are initially repaired by surgeons who do not specialize in such reconstructive surgery. Indeterminate surgical exploration and inappropriate timing of definitive reconstructive surgery are ubiquitous [Doumenc *et al*, 2016].

The problem of increasing the success of repair of extrahepatic bile ducts and reducing the frequency of recurrence of restenosis after recovery is a serious problem in hepatobiliary surgery. Evidence has shown that the success of definitive reconstructive surgery for extrahepatic bile duct strictures depends on preoperative accurate assessment of the type of injury, selection of appropriate surgical procedures, reasonable repair techniques, and application of precise biliary surgery.

Thus, today many aspects of surgical treatment and prevention of biliary tract injuries remain controversial. In this regard, the search for new effective methods and means of eliminating CSEBD is relevant.

One of the most important changes in recent years has been the rapid development and evolution in the design of metal biliary stents. For many years, metal stents designed for the vascular system were the only option for the biliary interventionist, but there are now many specialized stent systems designed specifically for biliary use. Thus, one of the means in abdominal surgery can be an alloy based on titanium nickelide, which is widely used in medicine due to its high biocompatibility with body tissues [Dambaev *et al.*, 2007]. In this regard, the introduction of superelastic titanium nickelide structures with a shape memory effect was another step in the development of reconstructive hepatobiliary surgery.

Purpose of this study is identify effectiveness of surgical treatment of patients with cicatricial strictures of the extrahepatic ducts using superelastic titanium nickelide structures in comparison with traditional methods of surgical treatment.

EXPERIMENTAL

A retrospective analysis of 81 patients' case histories with CSEBD who were hospitalized in the Novosibirsk State Medical University clinics General Surgery Department for the period from 2001 to 2008 was carried out. Depending on the surgical intervention methods, all patients were divided into 2 clinical groups: 1) Group I (main) included 38 patients who received titanium nickelide implants with a memory effect during surgical treatment of CSEBD; 2) Group II (comparison) included 43 patients operated on with traditional methods of surgical treatment.

Long-term results of surgical treatment in terms of quality of life were monitored using MOS SF-36 and the GSRS questionnaire 12 months after surgery. Statistical processing of material was carried out using Excel 7.0 for Windows XP, Statistika for Windows 6.0. The significance of differences in mean values was determined based on Student's t-criteria. The relationship between the indicators is proven using the Pearson correlation coefficient.

RESULTS AND DISCUSSION

In patients of both groups, before surgery, all scores on the SF-36 general questionnaire were reduced. The indicators of Role Physical Functioning and Role Emotional Functioning were the most reduced to 0.00%, as well as pain syndrome, general health and social functioning in both comparison groups. A significant intensity of pain leads to a limitation in the activity of patients, to a decrease in the patient's assessment of their health and its prospects, as well as to a decrease in social activity in patients of both comparison groups. In the immediate postoperative period, all scores on the SF-36 questionnaire began gradually increase. Accordingly, in long term, the following results are achieved (Table 1 and Figure 1).

Table 1: Comparison of quality of life indicators in patients with cicatricial strictures of the extrahepatic bile ducts and biliodigestive anastomoses according to the SF-36 questionnaire in the long-term period.

Indicators	Groups	
	Main	Comparison
Physical functioning (PF)	95.59±1.23	88.71±2.46
Role physical functioning (RPF)	95.45±3.54**	84.04±5.73
Pain syndrome (PS)	94.64±2.13*	68.14±3.63
General health (GH)	87.45±2.98**	75.32±2.93
Viability (V)	87.55±1.67**	73.82±2.75
Social functioning (SF)	97.16±1.14**	83.98±2.68
Role emotional functioning (REF)	100±0.00**	82.62±4.61
Mental health (MH)	89.18±1.44*	74.93±2.18
Physical component of health (PH)	50.97±0.60 **	49.88±0.44
Mental component of health (MH)	58.40±0.51*	51.15±1.20

Remarks: * - p < 0.001, ** - p < 0.05, compared to the comparison group

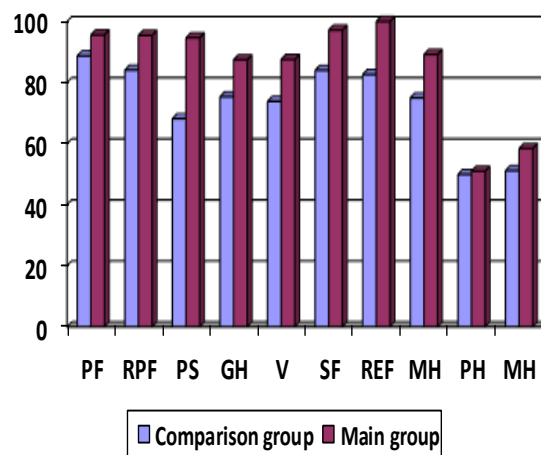


Figure 1: Correlation of QoL indicators in patients with cicatricial strictures of the extrahepatic bile ducts and biliodigestive anastomoses in both comparison groups according to the SF-36 questionnaire in the long-term period.

When processing the data obtained, it was found that for scales all indicators according to the SF-36 questionnaire, there is a significantly positive, strong correlation between all indicators of PF, RPF, PS, GH, V, SF, REF, MH, PH and MH scales ($r = 0.457$ to 0.918 , $p < 0.001$).

Further results analysis obtained by authors on patients with cicatricial strictures of the extrahepatic bile ducts and biliodigestive anastomoses in comparison group using the SF-36 questionnaire revealed a significantly lower quality of life compared to the main group according to the PS and PH scales ($p < 0.001$), and according to the scales of V, SF, REF, GH and MH - $p < 0.05$.

We also see that in patients with cicatricial strictures of the extrahepatic bile ducts [Shalimov *et al*, 1962] and biliodigestive anastomoses of the main group, the PF, RFF, PS, and SF scales have values above 90%, and the REF scale was 100%, which shows us an increase in QoL in patients of the main group in long-term period after operations. And in comparison with patients operated by traditional methods in comparison groups, the values are higher. Thus, in the long-term period, the SF-36 values in total significantly ($p < 0.05$) have higher values in patients with cicatricial strictures of the extrahepatic bile ducts and biliodigestive anastomoses in the main group, who used titanium nickellide stents, compared with the comparison group operated by the traditional method.

The results of QoL indicators in patients with cicatricial strictures extrahepatic bile ducts and biliodigestive anastomoses according to the GSRs questionnaire are presented in Table 2 and Figure 2.

Table 2: Comparison of QoL indicators in patients with cicatricial strictures extrahepatic bile ducts and biliodigestive anastomoses according to the GSRs questionnaire.

Indicators	Groups	
	Main	Comparison
AP	1.23±0.14**	1.68±0.14
RS	1.11±0.04**	1.67±0.12
SC	1.12±0.07	1.22±0.07
IS	1.14±0.07*	1.72±0.12
DS	1.05±0.03	1.17±0.07

Remarks: * - $p < 0.001$; ** - $p < 0.05$ compared to the comparison group

According to the PS scale, among patients of the main group, the indicator was at the level of 94.64% (± 2.13), and in the comparison group, it was 68.14% (± 3.63), which is 26.5% higher. This means that the patients of the main group are almost not worried about the pain syndrome, and, consequently, their QoL is higher than in the comparison group. A significantly strong and positive correlation was found between the GSRs questionnaire scales scores (AP, RS, SC, IS, DS) at the level of $r = 0.679$ to 0.904 ($p < 0.05$).

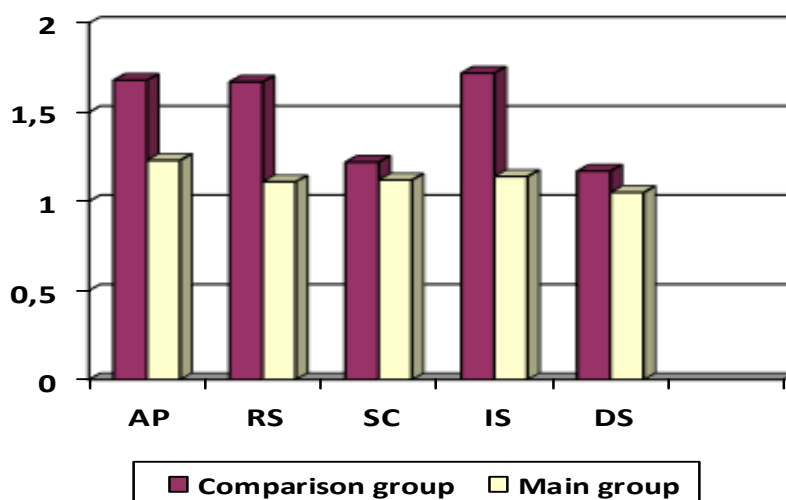


Figure 2: Comparison of QoL parameters in patients with cicatricial strictures of the extrahepatic bile ducts and biliodigestive anastomoses according to the GSRs questionnaire in the long-term period.

In the long-term period, the GSRs indicators (especially AP, RS, IS) in total significantly ($p < 0.05$) have higher values in patients with cicatricial strictures of the extrahepatic bile ducts and biliodigestive anastomoses in the comparison group compared to the main group. Based on these results, it can be said that the QoL of patients with cicatricial strictures of the extrahepatic bile ducts and biliodigestive anastomoses in the main group is higher compared to the comparison group. At the same time, their physical and emotional activity and social functioning increase, which indicates an improvement in QoL in patients of the main group in the long-term period.

When comparing scores of the SF-36 and GSRs questionnaire scales with each other using the Spearman correlation coefficient, it was found that there is a significantly significant, moderate inverse correlation of the scores of the PS and IS scales (GSRs) with the PF, RFF, PS, GH and V (SF-36), respectively ($p \leq 0.001, < 0.05$). The indicator of the RS scale (GSRs) with the PF and RFF scales (SF-36), and the CS scale (GSRs) with the PF, GH, V and SF scales (SF-36), also has a significantly significant, moderate inverse correlation of indicators between itself ($p < 0.05$). The DS scale (GSRs) has no correlation with all SF-36 scales ($p > 0.05$) (Table 3).

Table 3: Correlation of the scales of the GSRs questionnaires with SF-36 in patients with cicatricial strictures of the extrahepatic bile ducts and biliodigestive anastomoses in the long-term period.

SF-36 scales	Scales of the GSRs questionnaire				
	AP	RS	CS	IS	DS
PF	-0.652*	-0.533**	-0.633**	-0.523**	-0.212***
RPF	-0.650*	-0.581**	-0.333***	-0.582**	0.100***
PS	-0.504**	-0.382***	-0.373***	-0.434**	0.192***
GH	-0.633**	-0.376***	-0.526**	-0.469**	0.046***
V	-0.514**	-0.335***	-0.495**	-0.475**	0.331***
SF	-0.356***	-0.198***	-0.430**	-0.291***	0.171***
REF	-	-	-	-	-
MH	-0.368***	-0.342***	-0.286***	0.290***	0.191***

Remarks: * - ≤ 0.001 ; ** - < 0.05 ; *** - > 0.05

CONCLUSION

Advances in both technology and methods over the past three decades have further expanded the scope of biliary interventional practice. In particular, the biliary stent design has undergone major changes and continues to evolve, expanding the role of stents in both benign and malignant diseases. The introduction of the titanium nickelide alloy, which has the properties of superelasticity and thermoform memory, has led to the introduction of a new generation of stents. These stents show increased flexibility and conformity compared to their stainless steel predecessors.

In summary, it can be seen in all indicators that the use of titanium nickelide stents has an advantage over traditional surgical treatment of patients. Thus, analysis of data characterizing the patients' life quality revealed that in the main group of patients, the scores calculated as a percentage are higher than in the comparison group. It can be seen that

patients of the main group rated their physical performance, physical condition, energy, emotional state, general health higher than in the comparison group. In patients using the titanium nickelide stents for long-term period, the quality of life is higher than in patients of comparison group operated by traditional methods.

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