

Quality of Life in Patients with Background of Iatrogenic Bile Duct Injury

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Abstract

Background There are only a few reports regarding the quality of life of patients who underwent a complicated cholecystectomy with an iatrogenic bile duct injury (IBDI); the results have been heterogeneous and realized with unspecific measures.

Methods The objective was to determine whether the quality of life of the subjects with a history of IBDI repaired with bilioenteric derivation is modified in the long term with respect to a control group, for which a group of patients with a history of IBDI (group A) was compared with a group of patients with a history of uncomplicated cholecystectomy (group B). Two different measures were used: on the one hand, the SF-12 questionnaire and on the other hand, a questionnaire was implemented where the patient could determine by himself which variables define his quality of life.

Results A total of 46 patients were included in group A and 51 in group B. The analysis of the SF-12 questionnaire showed a statistical significant reduction in 4 of 8 of the evaluated parameters (general health, physical functioning, physical role and social functioning) in group A in comparison with group B. If a more specific questionnaire is used, the results are similar, with a statistically significant reduction in the quality of life within the group A (0.03).

Conclusions We conclude that the quality of life of patients with a history of bilioenteric derivation due to an IBDI decreases significantly compared to patients with uncomplicated cholecystectomy.

Introduction

Since the first cholecystectomy was accomplished by Karl Langebuch in 1882, it has become the most common surgery realized by general surgeons of the western world. Moreover, it is associated with a relatively low rate of morbidity and mortality in patients with low risk factors and when the surgery is done by an experienced surgeon; nevertheless, some complications are observed and the

possible lesions can endanger the integrity and life of the patient. The morbidity is variable, ranging from 2.3 to 23% [1] and a mortality from 0.07 to 0.17% [2, 3].

Iatrogenic bile duct injuries occur with an incidence of 0.06–1.09% [4–10], being in about two-thirds of the cases major lesions (with loss of biliodigestive continuity). The prognosis depends mainly on the experience of the surgeon who realizes the reconstruction surgery, the coexistence of vascular lesions and the degree of the injury, where the long-term success rate in cases repaired in specialized centers achieves 90%, and the 17% in non-specialized centers [11].

The success of a bile duct surgery can be measured by many technical parameters, like the bleeding, need for a second intervention, stenosis or days of hospitalization to

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mention a few examples. However, the final objective of this procedure, which the surgeon should not lose sight of, is to recover the physical and emotional well-being of the patient. Therefore, the quality of life is one of the best parameters to evaluate the result of a lesion-reparation process, which until now has been underestimated and thus no specific instrument for the evaluation is established yet.

Defining the quality of life is complicated, because it designates conditions in which a person lives, that make their existence pleasant and worthy of being lived, or else, they fill it with affliction. According to the WHO, it is defined as “the individual’s perception of his place in the existence, in the context of the culture and value system in which they live and in relation to their goals, expectations, standards and concerns.” However, this concept is extremely subjective and very related to the society in which the individual exists and develops. Therefore, it is difficult to design an instrument to estimate the quality of life and which could easily be used during follow-up interviews.

At present, the most used questionnaire worldwide to evaluate the quality of life is the SF-36, which has been translated into more than 20 languages and is considered as the standard measure [12]. Nevertheless, it might be difficult to implement as it has a high number of questions, which consume a lot of time. As a result, in the year of 2002 the developers of SF-36 have suggested a shorter form with only 12 items (SF-12) with a clearer and easily understandable language. So, it was possible to reduce the application time and get a better acceptance of the respondents.

The main strategy to interpret the results is based on the comparison of a reference group, which indicates the standard value for every parameter, allowing a comparison between two populations. Using these questionnaires for individuals undergoing biliodigestive derivation due to IBDI, the reference group are cholecystectomized patients without complications.

Materials and methods

The objective of the present study was to determine whether the quality of life of an individual who underwent a complicated cholecystectomy with a complex lesion of the bile duct is modified during a long-term observation. The present study was performed during the period from April 2017 to October 2017 and took place in the Clinic of Hepatobiliary and Pancreatic Surgery (HPB) of the “Hospital General de México.” The study population was divided into two groups: One group were patients who came to a follow-up visit during the study period with the background of IBDI more than 1 year ago and which were treated with a bilioenteric derivation (group A). The

control group was obtained randomly from the records of patients who underwent uncomplicated cholecystectomy in our hospital and who agreed to come for an interview (group B).

To evaluate the quality of life, 2 different measures were used: on the one hand, the second version of the questionnaire SF-12 (questionnaire 1) and on the other hand, we create a questionnaire (questionnaire 2) of one direct question about how the individual perceives his quality of life (Table 1). Both questionnaires were applied to patients who met the inclusion criteria.

The statistical analyses were performed with SPSS software version 21 using measures of central tendency for the baseline characteristics of the study population and Student’s *t* test for the results of the questionnaires.

Results

Of the initial sample of 116 patients (group A: 49, group B: 67), 19 were excluded because they did not accept to participate in the interview. The final sample included 97 participants (group A: 46, group B: 51).

The baseline characteristics were similar in groups A and B regarding age ($p = 0.42$), gender ($p = 0.49$) and time of evolution ($p = 0.38$) since the surgical procedure. However, the surgical approach to cholecystectomy differed significantly ($p = 0.03$) with a higher frequency of laparoscopic approach in the control group (Table 2). The timing of repair after IBDI was 36.5 days on average.

Most of the patients in the group A had Bismuth type II lesions ($n = 23/50\%$), following lesions Bismuth type III ($n = 17/36.9\%$), Bismuth IV ($n = 3/6.5\%$) and remodulations of previous biliodigestive derivations ($n = 3/6.5\%$). According to the type of reparation, the 3 cases of Bismuth IV were resolved through a double hepaticojejunostomy, while in the other 43 cases (93.5%) a biliodigestive derivation type Hepp–Couinaud was realized.

Three patients (6.5%) are in a protocol of dilatation of the biliary anastomosis due to a stenosis that consists in the placement of a mixed percutaneous transhepatic biliary drainage (which passes the anastomosis and is situated in the intestinal lumen), initially with a diameter of 8 French and with quarterly progressive replacements up to a variable diameter, generally 20–22 French. These patients had underlying lesions of Bismuth II ($n = 1$), Bismuth III ($n = 1$) and Bismuth IV ($n = 1$), this last patient with a double percutaneous biliary drainage (for the left and right anastomosis).

The parameters evaluated through SF-12 (questionnaire 1) are: physical functioning, role limitations due to physical problems, pain, general health, vitality, social functioning, role limitations due to emotional problems and

Table 1 Questionnaire 2

Do you think that your quality of life, under the concept that you understand by quality of life, has changed since your cholecystectomy until today?

Options:

- 1) Yes, improved
- 2) No, it is the same
- 3) Yes, it is slightly worse
- 4) Yes, it is a lot worse

mental health. There was a statistical significant reduction in group A in contrast to group B in general health, physical functioning, role limitations due to physical problems and social functioning. However, in the other parameters no significant difference was found (Table 3).

According to questionnaire 2, the majority of patients in both groups concluded that their quality of life improved compared to the period prior to their cholecystectomy (45.6% group A and 60.8% group B) and only 28.3% of patients with IBDI and 13.7% of the control group referred a detriment (Table 4). The statistical analysis with Student's *t* test about this result demonstrated a significant

difference in favor of the control group with a better quality of life.

Discussion

At present, there are only a few studies about the quality of life with patients following an IBDI. According to different authors, there can be found no difference when compared to a control group of uncomplicated cholecystectomized patients [13], or well a significant reduction regarding only the emotional scores [14], in the emotional and physical functioning [15, 16], or in the emotional, physical and social state [17].

In relation to these inconsistent results, Landman et al. [18] in a meta-analysis concluded that there is a statistical significant tendency toward an emotional detriment of the quality of life, which is constant in different studies (OR 38.42) and an inconsistent not significant tendency regarding the physical and social aspects. Nevertheless, there are other studies which showed no significant difference in any of the analyzed aspects. An interesting result was that the studies realized with a follow-up period less

Table 2 Baseline characteristics

| Group | Age | Female/male | Follow-up ^a | Laparoscopic surgery ^b |
|---------|--------------------|---------------------|------------------------|-----------------------------------|
| Group A | 41.3 years (18–73) | 36/10 (78.3%/21.7%) | 49.5 month (12–162) | 25 (35.7%) |
| Group B | 40.6 years (22–68) | 40/11 (78.4%/21.6%) | 57.6 month (14–240) | 37 (72.5%) |
| | <i>p</i> = 0.42 | <i>p</i> = 0.49 | <i>p</i> = 0.38 | <i>p</i> = 0.031 |

^aThe follow-up time is measured from the initial cholecystectomy

^bIndex surgery (cholecystectomy) performed by laparoscopic approach

Table 3 Results of questionnaire 1

| Parameter | Question | Group A | Group B | Pro | <i>p</i> |
|--|----------|---------|---------|---------|----------|
| General health | 1 | 2.86 | 2.31 | Group B | 0.002 |
| Physical functioning | 2 | 2.74 | 2.94 | Group B | 0.03 |
| | 3 | 2.58 | 2.9 | Group B | 0.008 |
| Role limitations due to physical problems | 4 | 8/46 | 4/51 | Group B | 0.78 |
| | 5 | 10/46 | 0/51 | Group B | 0.0001 |
| Role limitations due to emotional problems | 6 | 13/46 | 12/51 | Group B | 0.28 |
| | 7 | 8/46 | 10/51 | Group A | 0.40 |
| Pain | 8 | 1.3 | 1.35 | Group A | 0.27 |
| Mental health | 9 | 2.2 | 2.22 | Group A | 0.46 |
| | 11 | 4.77 | 4.96 | Group B | 0.13 |
| Vitality | 10 | 2.37 | 2.33 | Group B | 0.43 |
| Social functioning | 12 | 4.79 | 5.33 | Group B | 0.005 |

Table 4 Results questionnaire 2

| | Group A (n = 46) | Group B (n = 51) | p |
|---------------------|------------------|------------------|---------|
| Improvement | 21 (45.6%) | 31 (60.8%) | 0.03415 |
| Equal | 12 (26.1%) | 13 (25.5%) | |
| Slight worsening | 9 (19.6%) | 5 (9.8%) | |
| Important worsening | 4 (8.7%) | 2 (3.9%) | |

than 6 years had the tendency to report a significant global reduction in the quality of life, while the studies with a longer follow-up time demonstrated no difference. However, there could not be found an explanation for this phenomenon.

It should be taken into consideration that in some studies there is a patient loss from over 15% [19]; therefore, their quality of life is not evaluated; it is possible that the inclusion of these data could modify the results. Moreover, the published articles include only patients with successful biliodigestive derivations; in the present protocol, all patients were included, even those with stenosis, so there was a better reflection of what a biliodigestive derivation implies on the quality of life.

A considerable bias is the lack of a standardized measure, specifically aimed at the quality of life after a biliodigestive derivation, which makes the interpretation of the results published so far unreliable [18].

The available questionnaires are based on very general questions that may or not be related to the item that is being evaluated, an IBDI. To create a questionnaire for reflecting the quality of life is a challenge as it is a very subjective topic.

For this reason, a second questionnaire was implemented in which the perception of the individual about himself is evaluated, allowing the patient to determine freely the aspects that determine his quality of life. The SF-12 is based on questions which may or not be determining the patient's quality of life, while some fundamental aspects are probably not taken into consideration.

Our results show a statistical significant reduction in 4 of 8 parameters from the SF-12 (questionnaire 1). Contrary to what can be observed in other publications [14–16], the mental health and role limitations due to emotional problems in the present study are not reduced, while in the aspects of role limitation due to physical problems, physical functioning, social functioning and general health had a statistical significant reduction.

In the same way, the questionnaire of 1 direct question (questionnaire 2) indicates a significant difference between both, favoring the control group. Unexpectedly, the most common response was that quality of life improves both, in the IBDI and in the control group. An explanation could be

the remission of symptoms caused by the disease which led to the cholecystectomy, usually abdominal pain.

Conclusions

After performing two different questionnaires of evaluation, we conclude that the quality of life of the patients undergoing a bilioenteric derivation due to an IBDI is reduced significantly if compared to a control group of patients undergoing uncomplicated cholecystectomy.

Compliance with ethical standards

Conflict of interest There are not any financial competing interests (political, personal, religious, ideological, academic, intellectual, commercial or any other) to declare in relation to this manuscript.

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