

Evaluation of iliococcygeal fixation procedure for pelvic organ prolapse: preoperative properties and short term postoperative outcomes

Pelvik organ prolapsusu için iliokoksigel fiksasyon prosedürünün değerlendirilmesi: preoperatif özellikler ve kısa dönem postoperatif sonuçlar

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ABSTRACT

Aim: The aim of this study was to evaluate the short-term outcomes of patients who underwent iliococcygeal fixation (ICF) for the surgical treatment of pelvic organ prolapse (POP) and to assess the safety and feasibility of the ICF procedure.

Patients and Methods: Our study is retrospectively done with the data of 50 POP patients who underwent ICF in our clinic within the dates 01.04.2022 and 31.03.2024. A total of 44 women were found to be eligible for follow-up. Demographic data and pre- and post-operative clinical data at 3 months were assessed.

Results: According to the findings of our study, the difference between the median duration of surgery in NSD and CS patients is statistically significant, and the duration of surgery is longer in NSD patients (80 minutes (70-85) vs 60 minutes (50 -67,5), (p<0,05)). Only one recurrence, one hematoma and infection, and one bladder injury had occurred.

Conclusion: According to our study, ICF is a safe, durable and surgically feasible procedure that can be done concomitantly with other procedures. Thus, we strongly advocate this procedure until the ideal mesh is found since it avoids many serious complications of SSLF.

Key Words: Pelvic organ prolapse, sacrospinous ligament fixation, iliococcygeal fixation

ÖZ

Amaç: Bu çalışmada; pelvik organ prolapsusu (POP) nedeniyle, cerrahi tedavisi için iliokoksigel fiksasyon (ICF) uyguladığımız hastaların kısa dönem sonuçlarını araştırmayı ve ICF prosedürünün güvenilirliğini ve uygulanabilirliğini değerlendirmeyi amaçladık.

Hastalar ve Yöntemler: Çalışmamız 01.04.2022 ve 31.03.2024 tarihleri arasında kliniğimizde ICF uygulanan 50 POP hastasının verileri retrospektif olarak değerlendirilmiştir. Toplam 44 hasta çalışmada değerlendirme kriterlerine uygun bulundu. Hastaların demografik verileri ile preoperatif ve postoperatif 3. Aydaki klinik verileri değerlendirildi.

Bulgular: Çalışmamızın bulgularına göre, NSD ve CS hastalarında ortalama ameliyat süresi arasındaki fark istatistiksel olarak anlamlıdır ve NSD hastalarında ameliyat süresi daha uzundur (80 dakika (70-85) vs 60 dakika (50 -67,5), (p<0,05)). Sadece bir rekürrens, bir hematoma ve enfeksiyon ve bir mesane yaralanması meydana geldi.

Sonuç: Çalışmamıza göre, ICF güvenli, dayanıklı ve diğer prosedürlerle birlikte yapılabilen cerrahi olarak uygulanabilir bir prosedürdür. Bu nedenle, SSLF' nin birçok ciddi komplikasyonunu önlediği için ideal yöntem bulunana kadar bu prosedürü şiddetle savunuyoruz.

Anahtar Kelimeler: pelvik organ prolapsusu, sakrospinöz ligament fiksasyonu, iliokoksigel fiksasyon

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Introduction

Pelvic organ prolapse (POP), is one of the most frequently encountered diseases in the female population, especially in the elder age group [1]. It is reported that 11.1% of all women would experience a surgical procedure for this problem until the age of 80 [2]. Given the fact that we are living in an ever-growing older population, the graveness of the condition is self-evident. Since the usage of synthetic meshes is either banned or not advised after the announcements of the U.S. Food and Drug Administration, native tissue repair techniques are re-popularized to overcome this complex problem. The reconstruction of pelvic apical support remains as the most challenging obstacle in the field of urogynecology. Various surgical procedures are proposed to treat the condition such as sacrospinous ligament fixation (SSLF), sacrocolpopexy or hysteropexy, or other techniques such as lateral suspension. Nevertheless, the heritage of using paravesical space to anchor synthetic mesh kits to sacrospinous ligaments has proven the versatility and safety of utilizing an anterior vaginal approach to accomplish sacrospinous ligament fixation rather than using a posterior approach [3, 4].

Cespedes was the first to describe anterior SSLF and advocated the advantages of this approach when compared to classical unilateral SSLF (Richter's procedure) [3, 4]. However, neither SSLF nor abdominal sacrocolpopexy was free of complications such as bleeding or persistent buttock pain and, both also had considerable recurrence rates. When considering the pathophysiology of the apical prolapse, i.e. the loss of ligamentous support of Arcus Tendineus Fascia Pelvis, it seems more rational to mimic the original anatomy when treating this problem. Iliococcygeal fixation (ICF) was first described by Inmon and later advocated by Shull et al and Meeks et al. [5, 6]. Overall, the data shows that ICF has better or comparable anatomic results together with less serious complications. With this perspective, ICF has been utilized to correct apical compartment defects in our clinic since 01.04.2022 together with other procedures when needed or alone. In this study, we wanted to document its safety, feasibility (in terms of operation duration, bleeding amount), and short-term outcomes of

this procedure.

Patients and Methods:

Our study is retrospectively done with the data of 50 POP patients aged between 40-70 years who underwent ICF in our clinic within the dates 01.04.2022 and 31.03.2024 and were followed up for a minimum of 3 months. Patients with gynecologic malignancy, pelvic mass, fertility desire, and younger than adolescent age were not included in the study. Six cases were excluded from the study due to incomplete data. Demographic data and pre- and postoperative clinical findings of a total of 44 patients were evaluated. Demographic data such as age, gravida, parity, history of D&C and prior surgeries, comorbidities and family history were noted. As clinical findings; preoperative ultrasound examination, magnetic resonance imaging (MRI) and PAP smear results were evaluated. Other surgical procedures done concomitantly with ICF, type of anesthesia, duration of the operation, postoperative complications, pre- and postoperative hemoglobin level, late postoperative complications, perioperative hemorrhage and the presence of infection were also noted.

Statistical Method

The data were analyzed with a package of software (SPSS 28). The normal distribution of numeric values was tested by the Shapiro-Wilk test. The normally distributed numeric values were expressed by average \pm SD, minimum, and maximum values. The values that are not normally distributed were expressed by Median (1st Quartile (Q1)- Third quartile (Q3)), minimum and maximum values. Categorical variables were summarized as numbers and percentages.

Mann-Whiney U test was utilized to compare two independent groups. Whereas, the Wilcoxon test was used for dependent groups. The statistical significance value (p) was taken as <0.05.

Results

A total of 50 cases were retrospectively reviewed. After the exclusion of six cases, because of missing data, a total of 44 women were found to be eligible for follow-up analysis. Demographic data, risk factors, and, some other general information

about the surgeries performed are summarized in Table 1.

Table 1 Demographic data, risk factors, and surgical characteristics of patients

	Total number of patients =44 (n)
Age	56,11±7,70 (41,00- 73,00)
Gravidity	3,00 (2,00-4,00)
Parity	3,00 (2,00-4,00)
Live birth	3,00 (2,00-3,75)
Type of Delivery	
-Nulliparous	3 (6,8%)
-Vaginal birth	31(70,5%)
-Cesarian	10(22,7%)
Ultrasonographic finding	
Pathology detected	29 (65,9%)
Pathology not detected	15 (34,1%)
History of chronic disease	25(56,8%)
Hypertension	17 (38,6%)
Diabetes	4 (9%)
History of prior operations	22(50%)
Preoperative hemoglobin	13,30 (12,20-14,08)
Postoperative hemoglobin	11,30±1,28 (8,70-13,90)
Duration of surgery	75,00 (60,00-85,00)

Of the 44 patients who underwent VH for POP, ICF and CAP were also performed on 26 (59.1%) patients whereas ICF alone was performed on 7 (15,9%) patients (Table 2). 7 (15,9%) patients were operated under general anesthesia and 37 (84,1%) patients were operated under spinal anesthesia. While no complication occurred in 41 (93,2%) of the patients, 3 patients had the complications as follows: relapse in one patient (2,3%), hematoma and infection in one patient (2,3%), and bladder injury in one patient (2,3%). 18 patients (40,9 %) had a decrease in hemoglobin of 1-2 g/dL whereas only 2 patients (4,5%) had a decrease of more than 3 g/dL. A combination of VH and ICF alone was observed to have less surgery duration than combining VH and ICF with other surgery types such as CAP (Table 3).

According to the findings of our study, the difference between the median duration of surgery in NSD and CS patients is statistically significant and the duration of surgery is longer in NSD patients (80 minutes (70-85) vs 60 minutes (50 -67,5), (p<0,05)). There was a negative, weak, and statistically significant relationship between surgical time and gravida, parity, abortion, and

survival (p<0,005).

Table 2 Data on type of surgery and anesthesia and complications

	N	%
Surgery type		
VH+ ICF	7	15,9
VH+ ICF+ CAP	26	59,1
VH+ ICF+ CAP+ other	11	25,0
Anesthesia Type		
Spinal	37	84,1
General	7	15,9
Postoperative complication		
No	41	93,2
Yes	3	6,8
Complication type		
,00	41	93,2
Relapse	1	2,3
Hematoma+ infection	1	2,3
Bladder injury	1	2,3
Amount of decrease in hemoglobin		
None	2	4,5
0-1g/dL	9	20,5
1-2 g/dL	18	40,9
2-3 g/dL	13	29,5
3 g/dL and above	2	4,5
Infection		
No	43	97,7
Yes	1	2,3
Relapse		
No	43	97,7
Yes	1	2,3

VH: Vaginal hysterectomy, ICF: Iliococcygeal fixation, CAP: colporrhaphy

Table 3 Duration of surgery

	Type of Surgery		
	VH+ICF (n=7)	VH+ICF+CAP (n=26)	VH+ICF+CAP+ Other (n=11)
Duration of surgery (minutes)	70,00 (50,00-75,00)	75,00 (60,00-86,25)	80,00 (70,00-85,00)

VH: Vaginal hysterectomy, ICF: Iliococcygeal fixation, CAP: colporrhaphy

Discussion:

Our case series displays the surgical feasibility and, safety of ICF with comparable morbidity and anatomic success when treating pelvic organ prolapse (POP). POP is a disease with complex interactions with all interconnections within the pelvic floor and its resident organs. This nature of the pelvic floor is well depicted by the integral theory that considers the pelvic floor as a single unit. Hence any anatomic or functional derangement

that takes place in a certain compartment eventually affects the other compartments. De Lancey practically divided pelvic support into three compartments. Among these, apical support (Level III) might be considered as the hardest part to restore. To date, many surgical attempts have been made to correct the innate or acquired loss of support on this level. The major problem for restoring the apical support was to find a suitable anchoring site for a robust and durable repair. When synthetic mesh kits were introduced, this problem was seemingly solved by excellent anatomic outcomes reported by multiple studies utilizing these meshes. However, not much later a considerable number of complications regarding the usage of polypropylene mesh kits eventually led to their banning and removal from the market. This dichotomized the professional community regarding their usage. Some healthcare professionals expressed their frustration with their practices so that up-holding the utilization of mesh. They continued to believe that this concept should not be dismissed but ideal mesh search must continue. Others, on the other hand, adopted the legislative advice more rapidly and tried to minimize patient complaints such as pain, dyspareunia, erosion, or infection simply by avoiding the usage of synthetic meshes. Under the pressure of lawsuits, some reaching to millions of dollars of compensation fines, urogynecologists mostly started to convert back to native tissue repair techniques such as site-specific repair, SSLF, or SCP.

As a busy urogynecology unit, our clinic also adopted to utilize these conventional procedures while awaiting ideal mesh and conducted research studies with stem cells to overcome problems with polypropylene meshes.

The spinous process and sacrospinous ligament are believed to be one of the most convenient and strong anchoring sites to restore apical support. SSLF, therefore was found to be one of the most reliable procedures after the mesh kit debate. However, this procedure was hard to accomplish due to the proximity of the obturator neurovascular bundle with the ligament. Serious hemorrhage or neurologic injuries were reported inevitably by various studies [7]. Moreover, unilateral fixation resulted in significant deviation of the vaginal

axis which was the preferred method by many surgeons. Interestingly Medina et al. reported that total vaginal length was longer in patients treated with ICF when compared to SSLF [8]. On the other hand, the anterior approach popularized by the mesh kit applications, and using the fascia of the iliococcygeus muscle for the anchoring site avoided these unwanted events successfully. In a review, done by Sze and Karram, there was 3% persistent gluteal pain after SSLF procedures while there was none after ICF [9]. Although it included only 7 patients operated with ICF procedure, the study of Biler et al compared the results and complication rates of common suspension techniques. In their study, there was no reported complication in ICF procedure whereas there were 9 and 4 complications in abdominal sacrocolpopexy and SSLF procedures respectively [10]. In a 10-year follow-up study, ICF was also reported to provide efficient apical support with acceptable complication and recurrence rates [11]. ICF may also provide a more anatomical repair since it follows the original Arcus Tendinous Fascia Pelvis attachment, which is believed to be the major apical and lateral support in the pelvic floor.

This study shows that it is a safe and efficient method evidenced by only one recurrence, one hematoma and infection, and one bladder injury. It should be noted that all the ICF procedures carried out were done concomitantly with other major pelvic surgeries such as vaginal hysterectomy and/or colporrhaphy or other procedures. Therefore, complication rates cannot be segregated from these concomitant procedures. Nevertheless, the complication rates and recurrence rates can be considered very low even though the procedures were undertaken with other major operations. Our study has limitations since it is retrospective in design with a limited number of patients. Another weakness can be considered that our clinic protocols did not include quality-of-life measurements and disease-specific questionnaires. Due to the lack of preoperative POP-Q measurements in every case, we did not include it in our study results. The reason for recurrence was further analyzed. It was concluded that the suture material failure was the reason since the recurrence was reported by the patient with a snap-like sound feeling in the first week postoperatively. In the examination, the left-

hand side suture was found to be broken and this led to the recurrence of prolapse. This case was further treated with abdominal sacrocolpopexy with a successful outcome after 3 months.

Limitations: Limitations of our study that may have influenced our results include the fact that our study was retrospective, our follow-up period was short, and our clinical experience with the ICF procedure was only 2.5 years. Nevertheless,, the outcomes of our study may contribute to national data and/or the systematic reviews and meta-analyzes [12] which will be at least together with other studies on the subject from our country at least together with other studies on the subject from our country. It may also contribute to a clinical guideline [13] based on the results of other national and/or international studies, systematic reviews and meta-analyses related to our research topic and its results.

Conclusion: We believe that ICF is a safe, durable, and surgically feasible procedure that can be done concomitantly with other procedures. We strongly advocate this procedure until the ideal mesh is found since it avoids many serious complications of SSLF.

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