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## **Reconstructive Urology**

## Risk of Complications After Hydrocele Surgery: A Retrospective Multicenter Study in Helsinki Metropolitan Area

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#### **Abstract**

**Background:** Despite being one of the most frequent urological procedures, the risk estimates for complications after hydrocele surgery (hydrocelectomy) are uncertain. Decision-making about hydrocelectomy involves balancing the risk of complications with efficacy of surgery—a tradeoff that critically depends on the complication risks of hydrocele surgery.

**Objective:** To examine the 90-d risks of complications of hydrocele surgery in a large, contemporary sample.

**Design, setting, and participants:** We retrospectively reviewed all surgeries performed for nonrecurrent hydroceles conducted in all five Helsinki metropolitan area public hospitals from the beginning of 2010 till the end of 2018, and evaluated the complication outcomes.

**Outcome measurements and statistical analysis:** The following outcomes were evaluated: (1) risk of moderate or severe (Clavien-Dindo II–V) hydrocele surgery complications, (2) risk of reoperation due to a surgical complication, and (3) risk of an unplanned postoperative visit to the emergency room or outpatient clinic, all within 90 d after surgery.

Results and limitations: We identified 866 hydrocele operations (38 [4.3%] bilateral operations). A total of 139 (16.1%) patients had moderate or severe hydrocele surgery complications within 90 d after surgery. Of the 139 complications, 94 were (10.9% of all or 67.6% of patients with moderate or severe complications) Clavien-Dindo grade II, 43 (5.0% and 30.9%, respectively) grade III, two (0.2% and 1.4%, respectively) grade IV, and none grade V. A total of 45 patients (5.2% of all and 32.4% of those who had moderate or severe complications) required immediate reoperation due to complications. All together 219 operated patients (25.3% of all operated patients) had an unplanned visit to the emergency room. The retrospective study design limits the reliability of the results.

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**Conclusions:** Complications after hydrocele surgery are common and warrant further research. These estimates can be useful in shared decision-making between clinicians and patients.

Patient summary: We investigated the complication rates after hydrocele surgery and found that complications are common after a procedure often considered minor: every ninth patient had a moderate and every 20th a severe complication. Every fourth patient had an unplanned postoperative visit to the emergency room. ⊚ 2022 The Authors. Published by Elsevier B.V. on behalf of European Association of Urology. This is an open access article under the CC BY-NC-ND license (http://creative-commons.org/licenses/by-nc-nd/4.0/).

#### 1. Introduction

Hydroceles are common and often bothersome. Although hydrocelectomy is one of the most common urological surgeries, there is surprisingly little research on hydroceles. A recent epidemiological study from Sweden found that the annual incidence of men with hydrocele requiring medical assistance was approximately 60 per 100 000 men and the annual incidence of treatment for hydro- or spermatocele was approximately 17 per 100 000 men [1]. Treatment of hydrocele is required when subjective functional problems, such as pain, discomfort, or disability, are present [2]. Treatment options include surgery and aspiration with or without sclerotherapy. Patients should carefully be informed of the differences in the interventions, that is, the treatment protocol, cure rates, and complication risks. For the shared decision-making between clinicians and patients, reliable estimates of the complication risks are required.

The conventional approach in surgery is the Jaboulay-Winkelmann's technique where the hydrocele sac is everted behind the testes and the spermatic cord. The Lord's technique is a slightly less invasive plication technique for the treatment of hydrocele, which has been associated with a lower complication rate in some studies [3-5]. Needle aspiration with or without sclerotherapy is a substantially less invasive treatment option for hydrocele. A Cochrane metaanalysis published in 2014 found four randomized controlled trials (RCTs; with only 275 patients) comparing surgery versus aspiration-sclerotherapy in the treatment of hydrocele. There were fewer postoperative complications and more recurrences in the aspiration and sclerotherapy group. Infection and hematoma were reported in ten out of 120 (8.3%) and in seven out of 92 (7.6%) operated patients, and in two out of 155 (1.2%) and four out of 97 (4.1%) patients treated with aspiration and sclerotherapy. The risk estimates were, however, not statistically significant, possibly due to low statistical power (very few events) [6]. Earlier observational studies reported higher risks of complications (19-34%) after hydrocele and other benign scrotal surgery, but used heterogeneous definitions and variable grading, limiting their comparability [7–10]. Prompted by the dire lack of research on one of the most common urological procedures, we aimed to assess the complication rate after primary hydrocele surgery in a large contemporary patient sample using the modified Clavien-Dindo classification on reporting and grading of complications after urological surgical procedures by the European Association of Urology (EAU) Guidelines Ad Hoc Panel [11].

#### 2. Patients and methods

We retrospectively searched the electronic patient records for hydrocelectomies performed between January 1, 2010, and December 31, 2018, in each Helsinki metropolitan area public hospital that has a urology day-surgery unit (namely, Peijas, Hyvinkää, Porvoo, Lohja, and Raasepori hospitals). We used the code KFD20, according to the NOMESCO classification of surgical procedures [12] . All five hospitals used the same electronic patient record system during the 2010–2018 period. We did not include spermatocele operations, reoperations for hydrocele recurrence, or other scrotal operations. We included patients who were 16 yr or older at the time of the operation.

Normal protocol for hydrocelectomy is day surgery, where the patient leaves home a few hours after the surgery and no follow-up visits are planned. We extracted complication data by reading the patient database texts of the unplanned postoperative visits in the emergency room or outpatient clinic. We used the Clavien-Dindo classification for surgical complications [13] for grading the complications after hydrocele surgery. The grading system and examples in hydrocele surgery are presented in Table 1. In addition to the grading system, we defined the postoperative complications as hematoma, infection, seroma formation/early recurrence, and wound dehiscence.

We extracted the following outcomes from the patient records: (1) moderate or severe hydrocele surgery complications, classified as grade II–IV by the modified Clavien-Dindo classification on reporting and grading of complications after urological surgical procedures by the EAU Guidelines Ad Hoc Panel [11]; (2) reoperation due to surgical complications; and (3) an unplanned postoperative visit to the emergency room or the outpatient clinic, all within 90 d after surgery. The time between the postoperative visit and primary hydrocele surgery was recorded. If the patient was readmitted to the ward, the length of stay was recorded.

In addition to the endpoints described above, we collected data on age, American Society of Anesthesiologists (ASA) classification, body mass index (BMI), previous sclerotherapy (the agent used in the study area is polidocanol), size of the hydrocele (<300 ml as small and ≥300 ml as large), previous anticoagulation therapy, antibiotic prophylaxis, experience of the surgeon (urology consultant, senior resident, or junior resident), and surgical technique (ie, Jaboulay-Winkelmann, Lord, or resection).

Continuous variables were described by medians and interquartile ranges (IQRs) if the distribution was skewed, and if the distribution was normal, we described these variables by means and standard deviations (SDs). For the endpoint estimates and risk factor analyses, we used the 95% confidence interval (95% CI). For the risk estimate analyses, we used logistic regression and chi-square. The p values of <0.05 were considered statistically significant. Statistical analyses were conducted using SPSS version 26 (IBM Corp., Armonk, NY, USA) [14].

Grade	Clavien-Dindo	Examples after hydrocele surgery
Grade I	Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic, and radiological interventions. This grade also includes wound infections opened at the bedside Allowed therapeutic regimens are drugs such as antiemetics, antipyretics, analgesics, diuretics, electrolytes, and physiotherapy	The patient visits the emergency room after the operation when suspecting a complication. He might feel pain and discomfort. Swelling of the scrotum, subcutaneous hematoma and serous secretion of the wound might be detected. Reassurance and possibly analgesics are given. Bedside interventions, wound opening, and punction are classified into this group.
Grade II	Requiring pharmacological treatment with drugs other than those allowed for grade I complications (eg, antibiotics). Blood transfusions and total parenteral nutrition are also included	In addition to grade I findings and interventions, the patient might have temperature, the infection parameters might be elevated, and the wound might secrete pus. The clinician in the emergency room suspects a surgical site infection. Antibiotics are prescribed, either intravenous or perorally. The patient can be readmitted to the ward.
Grade III	Requiring surgical, endoscopic, or radiological intervention	An immediate reoperation is needed for a postoperative hematoma or surgical site infection. The operation is conducted in the operation room usually under general anesthesia, and the patient is taken to the ward.
Grade IV	Life-threatening complication (including central nervous system complications) requiring intensive care management	In addition to the immediate reoperation, the postoperative condition is so severe that a sepsis and/or organ failure has developed. Treatment in the intensive care unit is needed. Fournier gangrene is classified into this group.
Grade V	Death of a patient	Death occurs due to hydrocele surgery complication(s).

Table 1 - Clavien-Dindo classification of surgical complications with examples of hydrocele surgery complications

#### 3. Results

We identified 866 primary scrotal hydrocele operations performed by 116 different surgeons as primary operators. The median number of operations per surgeon on this 8yr study period was 3 (range 1-93, IQR -6 to 12). As many as 75 surgeons operated five or fewer hydroceles during the period, and many of these were trainees on a short working visit to the urology department as part of their general surgery training.

Of these 866 operations, 38 (4.3%) were bilateral. The median age of the patient at the time of surgery was 60 yr (IQR 48-68 yr), the mean BMI was 27.1 kg/m $^2$  (SD 4.49), 71 (8.2%) patients had received sclerotherapy before the operation, and 82.4% of patients did not receive antibiotic prophylaxis. Resident was the lead surgeon in 45.8% of the operations. Most of the operations (85.1%) were performed according to the Jaboulay-Winkelmann technique (Table 2).

Of the 866 patients, 139 (16.1%, 95% CI 13.7-18.7%) had moderate or severe (Clavien-Dindo grade II-IV) postoperative complications within 90 d after surgery. Of these patients, 94 (10.9% of all or 67.6% of patients who had moderate or severe complications) had Clavien-Dindo grade II, 43 (5.0% and 30.9%, respectively) grade III, two (0.2% and 1.4%, respectively) grade IV, and none grade V complications (Table 3). Of the two (0.2%) Clavien-Dindo group IV complications, one (0.1%) was Fournier gangrene and the other (0.1%) a sepsis that required intensive care.

A total of 45 (5.2%, 95% CI 3.8-6.9%) patients required reoperation within 90 d after surgery due to postoperative complications. In 41 (91.1%) out of 45 patients, the reoperation was due to bleeding or a large hematoma. Orchiectomy was performed in three reoperations as testicular necrosis was encountered. A majority (86.7%) of these severe complications were dealt with a single reoperation, but in two cases (4.4%) up to six reoperations were needed.

All together 219 (23.5%, 95% CI 22.4-28.3%) patients had an unplanned postoperative visit to the emergency room or the outpatient clinic. When no signs of moderate or severe postoperative complications were found, we classified the visit as a Clavien-Dindo grade I complication (Table 1). A total of 80 (9.2% of all or 36.5% of patients who had an unplanned postoperative visit) patients had an unplanned postoperative visit with no signs of moderate or severe postoperative complications (Table 3). Some patients had multiple postoperative visits due to pain and other complaints.

In addition to the severity grading, we recorded the type of the complication: hematoma, infection, seroma formation/early recurrence, and wound dehiscence (Table 3). Many patients with moderate or severe complications (n = 89; 10.2% of all patients, and 64.0% of patients with moderate or severe complications) had simultaneous complications, such as hematoma and infection, seroma, and/ or wound dehiscence.

For those 219 patients who had an unplanned postoperative visit to the emergency department or outpatient clinic, the median time to revisit was 11 d (IQR 5-17 d). In total 51 (5.9%) patients were admitted to the ward because of postoperative complications. The median length of stay at the ward because of postoperative complications was 4 d (IQR 2-7 d). One patient needed intensive care for 4 d.

The associations between the demographic factors and moderate or severe postoperative complications were analyzed. A history of previous unsuccessful sclerotherapy, obesity, and the experience of the surgeon significantly increased the risk of moderate or severe postoperative complications (Table 2).

#### 4. Discussion

In our large, contemporary sample of 866 patients, one in six (16.1%) patients experienced moderate or severe Clavien-Dindo grade II-IV complications after hydrocele surgery, including one in 20 (5.2%) with severe (Clavien-Dindo III or IV) complications requiring complication surgery. Every fourth (23.5%) patient had an unplanned postoperative visit (Clavien-Dindo grade I-IV complications). These risks are substantial for a nonmajor operation of a benign condition.

The complication rate in our study is comparable with other earlier, albeit much smaller, studies that focused on

Table 2 - Demographics and risk factors

Risk/demographic factor		Total	Moderate or severe postoperative complications $(n/\%)$	p value	Odds ratio (95% C
Age group				0.05	0.92 (0.82-1.02)
	<20	18	1/5.6		()
	20-29	52	6/11.5		
	30-39	66	18/27.3		
	40-49	194	20/21.3		
	50-59	191	32/16.8		
	60-69	254	40/15.7		
	70-79	156	20/12.8		
	>80	35	2/5.7		
ASA group	700	33	2/3.7	0.25	1.04 (0.83-1.30)
non group	1	259	35/13.5	0.23	1.04 (0.05 1.50)
	2	351	67/19.1		
	3	221	34/15.4		
	4	19	2/10.5		
	5	0	0		
	Missing data	16	U		
Dader massa imidae	Missing data	16		0.01	1.74 (1.15, 2.62)
Body mass index	130	C17	00/14.3	0.01	1.74 (1.15–2.63)
	<30	617	88/14.3		
	>30	187	42/22.5		
n : 1 .1	Missing data	62		0.01	4 77 (4 47 0 70)
Previous sclerotherapy			10/000	0.01	1.77 (1.17–2.70)
	Yes	71	19/26.8		
	No	795	120/15.1		
Size of the hydrocele				0.08	1.5 (0.97-2.33)
	Over 300 ml	386	75/19.4		
	Under 300 ml	254	35/13.8		
	Missing data	227			
Bilateral operation				0.39	1.42 (0.64–3.16)
	Yes	38	8/21.1		
	No	828	131/15.8		
Antithrombotic/anticoagulative medication				0.73	1.10 (0.70-1.70)
	Yes	190	32/16.8		
	No	676	107/15.8		
Antibiotic prophylaxis				0.26	1.30 (0.82-2.04)
	Yes	152	29/19.1		
	No	714	110/15.4		
Experience of the surgeon				0.02	0.73 (0.56-0.96)
	Junior resident	136	14/10.3		
	Senior resident	261	39/14.9		
	Consultant	469	86/18.3		
Surgical technique				0.75	0.83 (0.43-1.61)
	Winkelmann/Jaboulay	737	122/16.6		` '
	Lord	78	11/14.1		
	Resection	39	6/15.4		
	Orchiectomy	1	0		
	Missing data	10	<u> </u>		

Table 3 - Postoperative complications

Clavien-Dindo	Hematoma	Seroma/early recurrence	Infection	Wound dehiscence	Total of Clavien-Dindo grade group complications <sup>a</sup>
Grade I	50	24	7	15	80
Grade II	59	13	70	30	94
Grade III	40	2	30	10	43
Grade IV	1	0	1	0	2
Total	150	39	108	55	

<sup>a</sup> Many patients had simultaneous complications, such as hematoma and infection, seroma, and/or wound dehiscence.

benign scrotal and hydrocele surgery complications [7–10]. In earlier studies, the risk of any type of postoperative complications was between 19% and 34%. Only one earlier study [7], however, used the Clavien-Dindo classification for grading the complications. In their (vs ours) study, the respective grading did not substantially differ from our estimates: grade I in 40% in their study versus 36.5% in ours, grade II in 38% versus 42.9%, grade III in 22% versus 19.6%, grade IV in 0% versus 0.9%, and grade V in 0% in both. In a

recent study from Denmark, where there was a second cohort after focusing on perioperative hemostasis and post-operative activity restriction, the reoperation rate was higher than in our study: 7.2–9.2% versus 5.2% in ours [10].

The 2014 Cochrane meta-analysis included four small RCTs (a total of 275 patients) and compared aspiration with sclerotherapy to surgery [6]. The estimates regarding complications were, however, not precise due to low event rates. In addition, heterogeneous definitions and variable

grading had been used in the reporting of the complications in the RCTs [15–18], which further limited their suitability for pooling in the analysis. For example, in an Indian study [15], the rate of edema and hematoma after surgery was 35.7% compared with the 3.3% postsurgery hematocele rate in a Nepalese study [16]. In addition, patients were younger in the RCTs than in our study or in the earlier observational studies (mean age 45 yr [14] and median age 33 yr [15] compared with the median age of 60 yr in our present study).

There was very little centralization of hydrocele surgery as the 866 patients were operated by 116 different surgeons. Hydrocele surgery is often considered to provide good training in basic surgery skills. In our data, residents were the lead surgeons in 397 (45.8%) of the operations. This basic surgery concept might cause hydrocele surgery to be relatively overlooked in our clinics and partly explain the high complication rate. However, in the risk factor analyses, we did not see a higher risk of complications when residents were the main surgeons.

After hydrocele surgery, it can be difficult to distinguish the difference of typical postoperative tenderness and swelling of the scrotum from a mild postoperative hematoma, and in a retrospective study setting, it becomes even more difficult. In the Helsinki metropolitan area, there are no planned postoperative control visits after hydrocele surgery. An unplanned postoperative visit thus was considered a deviation from the normal postoperative course and classified as a Clavien-Dindo grade I complication. However, many of these may have been for normal postoperative situations and more of a sign of insufficient patient information. This is why we focused on moderate or severe (Clavien-Dindo grade II–IV) postoperative complications that are more reliably measured in a retrospective study setting.

The major limitations of this study are its retrospective design and data collection based on patient files. We organized no routine follow-up visits, did not use validated questionnaires to define the complications, or did not gather patient-reported outcome measures such as patient satisfaction. We relied on the assumption that the patients will contact the hospital if they encounter any important complications. This may not, however, be an important limitation as we included all hospitals with a urology department in the Helsinki metropolitan area in our study. Indeed, although the overall complication rate was probably somewhat higher (as some of the minor complications might have been managed in other institutes, such as health centers), all or almost all major complications were treated in our study hospitals.

The strength of our study is its large and contemporary sample of 866 patients. Indeed, our study is the largest study focusing on hydrocele surgery complications. We collected a substantial amount of data on patient and surgical characteristics (Table 2), which enhances the comparability of our cohort with the data of other studies. In our risk factor analysis, we saw a significantly higher risk of moderate or severe postoperative complications if the patient had a history of failed sclerotherapy, was obese, or was operated by a consultant. Obesity was considered a risk factor in

one previous study [7]. In this study setting, the risk factor analyses are however subject to substantial risks for selection and confounding biases. For instance, typically, consultants are more likely to operate more complex hydroceles than the residents, and antibiotic prophylaxis is used more likely if the surgeon suspects an elevated infection risk.

The concept that hydrocelectomy is an easy operation that can be performed by a surgeon with limited surgical experience should be omitted. Although educating the next generation of surgeons is important, more attention should be paid to teaching the correct operative technique and securing adequate patient flow for the operative team. Future randomized trials should examine the benefits and harms of different management options for hydrocele with the goal of improving patient outcomes.

#### 5. Conclusions

We observed a high risk for complications after hydrocele surgery in a large cohort of 866 men: one in nine patients experienced moderate complications after hydrocele surgery, and every 20th patient required reoperation due to severe surgical complications. These results highlight the importance of careful counseling of patients with a bother-some hydrocele.

**Author contributions:** Lauri Mäki-Lohiluoma had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: All Authors.

Acquisition of data: Mäki-Lohiluoma, Kilpeläinen, Järvinen, Söderström. Analysis and interpretation of data: Mäki-Lohiluoma, Kilpeläinen, Tikkinen, Sairanen.

Drafting of the manuscript: Mäki-Lohiluoma, Kilpeläinen, Tikkinen, Sairanen.

Critical revision of the manuscript for important intellectual content: Mäki-Lohiluoma, Kilpeläinen, Tikkinen, Sairanen.

Statistical analysis: Mäki-Lohiluoma, Kilpeläinen.

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