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Original research

Factors predicting chronic pain after open mesh based inguinal hernia repair: A prospective cohort study

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HIGHLIGHTS

- 932 open mesh based hernia repairs were analyzed utilizing two regression models.
- Recurrence, complication, mesh weight, baseline VAS and age predict chronic pain.
- Recurrence, complication, mesh weight and baseline VAS predict intensity of pain.

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ABSTRACT

Introduction: Chronic postherniorrhaphy pain is the foremost setback of today's inguinal hernia repair. Finding predictors for it affects implants, operative techniques and allows for preventive measures.
Methods: Prospectively collected data from 932 outpatient open inguinal hernia operations between 2003 and 2010 were subjected to regression analysis. Visual analogue scale score (VAS) at least a year after operation and a measurement of chronic pain at one year were the target variables.
Results: Chronic pain was present in 99 (11.5%) patients one year after operation. Independent predictors for the occurrence of chronic pain were positively recurrence (Odds ratio, OR 6.77 vs. no recurrence, P = 0.005), complication (OR 5.16 vs. no complication, P = 0.002), mid-density mesh (OR 2.28 vs. lightweight mesh, P = 0.012), higher preoperative VAS score (OR 1.15, P = 0.006) and negatively higher age (OR 0.98, P = 0.027).
Predictors for a higher postoperative VAS score were recurrence (regression coefficient, RC, 1.49 vs. no recurrence, P = 0.001), complication (RC 0.76 vs. no complication, P = 0.016), heavyweight mesh (RC 0.50 vs. lightweight mesh, P = 0.046) and higher preoperative VAS level (RC 0.10, P < 0.001).
Conclusions: Recurrence, complication, mesh weight, preoperative VAS score and age are predictors for the occurrence chronic pain after open mesh based inguinal hernia repair. Recurrence, complication, mesh weight and preoperative VAS score are predictors of postherniorrhaphy VAS level.

1. Introduction

The era of open mesh repairs as the primary operative treatment for inguinal hernia has lowered recurrence to an acceptable level. Instead, chronic postherniorrhaphy pain has emerged as one of the most significant adverse effects. Pain has been pooled in reviews to be present in 10–12% of patients while single studies report ranges reaching 37% [1–3]. Factors contributing to postherniorrhaphy pain are complex and not well understood [4]. For example higher age, laparoscopy and lightweight mesh types have been found to be associated with lower prevalence of chronic postherniorrhaphy pain and reoperation, postoperative complications, higher preoperative pain levels and lower preoperative optimism with higher prevalence [5–7]. Such findings have been somewhat inconsistent. Variable results may have emerged from adding miscellaneous operative techniques in different proportions in the analysis. Also, some of the larger studies with the aim to find risk factors for pain are based on patient recollection of preoperative pain levels. In this study the prospectively collected details of several uniformly executed open inguinal hernia mesh repairs under the same setting

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were subjected to statistical analysis in order to find out which patient or operation related factors were associated with chronic postherniorrhaphy pain and higher postoperative VAS scores.

2. Materials and methods

The details of 932 open mesh based inguinal hernia repairs accumulated during the following prospective studies with chronic pain as primary end point, similar study design and uniform execution. These ambulatorily operated consecutively recruited adults who each went through a modification of the tension-free repair in a similar setting were treated as a cohort. Reporting follows the STROBE statement [8].

Between March 2003 and August 2004 consecutive adult patients (n = 228) in a single ambulatory unit were randomized to receive under local anesthesia unilaterally or bilaterally a heavyweight (Premilene®, 82 g/m^2; B. Braun, Melsungen, Germany), a mid-weight (Premilene LP®, 55 g/m^2; B. Braun) or a polypropylene-polyglactin lightweight composite mesh (Vypro II®, 35 g/m^2 after absorption; Ethicon, Hamburg, Germany) for a primary or recurrent inguinal hernia [9].

From June 2007 till May 2009 consecutive adult patients (n = 302) in three ambulatory units were randomized to receive under local anesthetic unilaterally or bilaterally a mid-weight polypropylene mesh (Optilene®, 60 g/m^2, B. Braun) secured in position either with absorbable sutures (3/0 Dexon®, United States Surgical, Norwalk, Connecticut, USA) or butyl-2-cyanoacrylate tissue glue (Glubran®; GEM, Viareggio, Italy) for a primary inguinal hernia [10].

Between February 2008 and January 2010 consecutive adult patients (n = 394) in two ambulatory units were randomized to receive under local, regional or general anesthesia unilaterally either a lightweight polypropylene mesh (Parietene Light™, 38 g/m^2; Covidien, Dublin, Ireland) secured with non-absorbable sutures (2/0 Prolene®; Ethicon, Somerville, New Jersey, USA) or a self-fixating polypropylene-polylactic acid (PLA) lightweight composite mesh (Parietene ProGrip™, 40 g/m^2 after absorption; Covidien) for a primary inguinal hernia [11].

Eligible were all at least 18 year old patients medically fulfilling the criteria of day case surgery without a previous mesh placement. In every operation incision, dissection, mesh trimming and slitting for the spermatic cord and its placement had followed according to the tension-free concept by Lichtenstein and Shulman [12]. In operations utilizing absorbing attachment, instead of permanent sutures, interrupted absorbable sutures or 1–2 drops of tissue glue had been applied along the inguinal ligament and over the conjoined tendon as well as between mesh tails. The self-fixating prefabricated mesh had been pressed into position as advised by Chastan [13]. Hernia sac had been usually resected. Large sacs had been inverted with absorbable sutures. In all procedures the iliohypogastric, ilioinguinal and genitofemoral nerves had been identified and preserved whenever possible but resected where visibly damaged. Outcomes had been obtained by clinical visits. Study 3 patients had additionally been sent symptom questionnaires 2–4 years after the operation. All patients had given written informed consent (Helsinki Declaration) and the local ethics committees (Central Hospitals Mikkeli, Päijät-Häme, North Karelia and Helsinki University) had approved the trials.

Analysis included the following patient, operation and implant related predictors: sex, body mass index (BMI, kg/m^2), age upon operation, preoperative inguinal pain in Visual Analogue Scale (VAS), hernia type (indirect, direct, combined, recurrent), mesh type (heavyweight, mid-weight, lightweight), attachment method (permanent sutures, absorbable sutures, glue, PLA microhooks), anesthesia method (local, regional, general), duration of operation, complication (visible nerve damage, bleeding, hematoma, infection, combinations), time to follow-up and 1-year hernia recurrence. The dependent variables were chronic pain (yes/no) one year after operation in one regression model and postoperative inguinal pain in VAS in the other. A 100 mm line on paper where the patient ticked the current inguinal pain served as the Visual Analogue Scale. Mesh weight cut off points were chosen according to Bellon: light (35–50 g/m^2), mid (50–80 g/m^2), and heavy (>80 g/m^2) [14]. The following were taken as indicative of chronic postherniorrhaphy pain at one year after operation: patient's yes-answer regarding bothersome pain in the operated groin, continuous need for pain medication due to pain in the operated groin and pain or VAS score >30 at rest. Choice of VAS >30 as threshold was based on the concept of analgesic success and the cut off points: no pain (<10 mm), mild (10–30 mm), moderate (31–70 mm) and severe pain (>70 mm) [15–17].

Statistical analysis was carried out with IBM SPSS Statistics 22.0® (IBM, Armonk, New York, USA). Mann-Whitney-U-test was utilized to test continuous variables in unrelated samples. Wilcoxon signed-rank test was applied to continuous variables in related samples. Predictor variables were entered simultaneously in a multivariate binomial regression model to find those that were independently associated with presence of chronic pain at 1 year. Additionally, the variables were subjected to a separate linear regression model to yield predictors for higher scores in postoperative VAS 1–4 years after operation. Missing data was considered random. The regression models omitted any incomplete sets of variable measurement. An α of 0.05 was chosen to mark statistical significance.

3. Results

Of the original 924 patients 698 (75.5%) had a complete set of measurements for the binomial regression model and 642 (69.5%) for the linear regression model. Fig. 1 displays patient numbers through the study.

At one year, 99 (11.5%) of responders (n = 862) experienced chronic pain: 19 (2.2%) used pain medication continuously, 65 (7.5%) had bothersome pain and 57 (6.6%) had at least moderate pain at rest. Overall, preoperative mean VAS score at rest was 28 and at follow-up 6, ($P < 0.001$) in those providing an answer on both occasions (n = 675). Tables 1a–1c provide information on VAS behavior from various perspectives. By the second follow-up point of study 3 patients, one hernia recurrence was reoperated and 4 more hernias explored laparoscopically because of eventually transient pain: their follow-up VAS values after the reoperation were low and reoperation had no effect on pain prediction models.

Table 2 presents results from multivariate binary logistic regression analysis for chronic postherniorrhaphy pain at one year for the predictors modelled simultaneously. Adjusting for the remainder of predictors, significant independent predictors for chronic pain were positively recurrence, complication, preoperative VAS level and mid-weight mesh as well as negatively age. Adding attachment type (as non-penetrative vs. penetrative) in the logistic regression model yielded: mesh type $P = 0.057$ where mid-weight mesh compared to lightweight mesh returned OR 2.21, 95% CI 1.15–4.26, $P = 0.017$. Fixation type was statistically insignificant (data not shown). Other model results were effectively same as with the original model.

Table 3 displays predictors for a postoperatively higher VAS score (included was 'time to follow-up') modelled in linear regression. Higher VAS scores were independently predicted from: higher preoperative VAS scores, recurrence, complication and heavyweight mesh as well as general anesthesia.

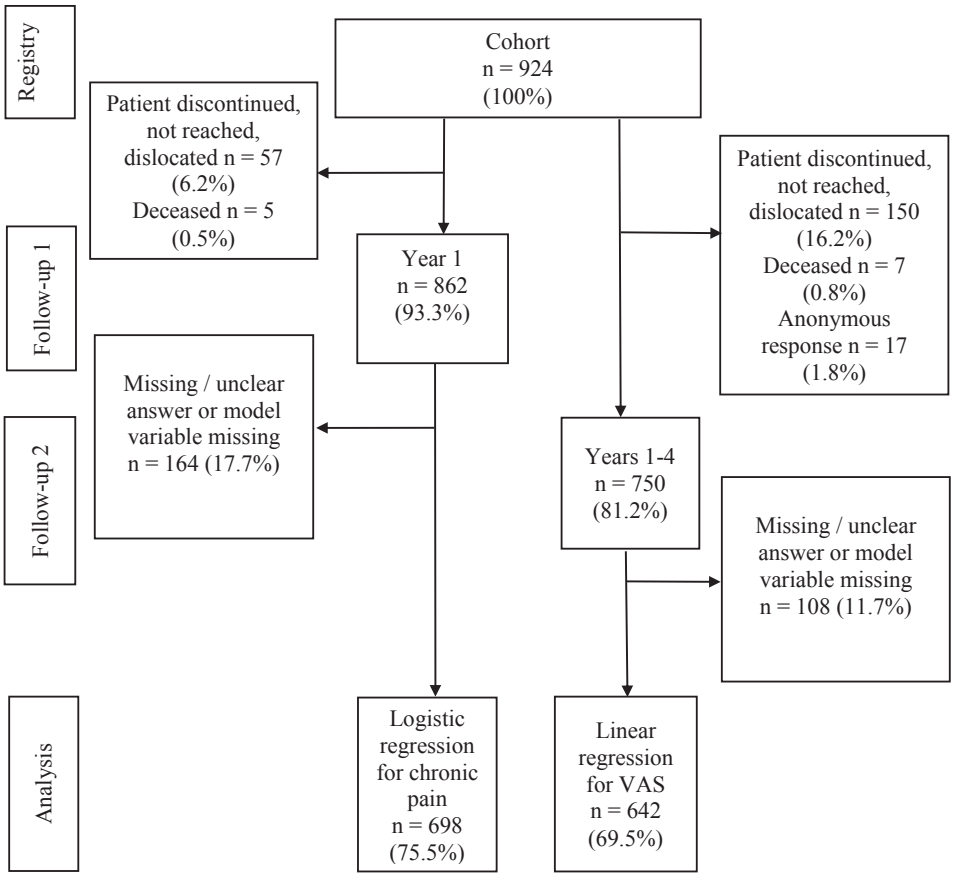

Fig. 1. Patient numbers through the study.

Table 1a
Significant groin pain preoperatively, answers on both occasions, n = 675.

	Preoperative VAS >30 (n = 230)	Preoperative VAS ≤ 30 (n = 445)	*P*[a]
Percent	34.1	65.9	
VAS, resting, preop	58 (16)	12 (11)	**0.005**
VAS, resting, postop	10 (18)	4 (11)	0.968
VAS Difference	−48 (22)	−8 (15)	**0.005**

Values are mean (standard deviation).
[a] Independent samples Mann-Whitney *U*-test.

Table 1b
VAS > 30 at follow-up (n = 675).

	VAS >30 postop (n = 42)	VAS ≤ 30 postop (n = 633)
Percent	6.2	93.8
VAS preop	50 (28)	26 (25)
VAS postop	54 (15)	3 (7)
VAS difference	+4 (32)	−23 (25)
P[a]	0.656	<**0.001**

Values are mean (standard deviation).
[a] Wilcoxon signed-rank test.

4. Discussion

The overall rate of chronic postherniorrhaphy pain found here (11.5%) compares well with earlier reports. Across the cohort, groin VAS scores for pain while resting were lower in the follow-up compared to the preoperative scores. Generally, high levels of preoperative groin pain (VAS > 30) were especially well counterbalanced afterwards (Table 1a). These findings indicate that, overall, open mesh surgery reduces pain from inguinal hernia. However, in patients having at least moderate pain (VAS > 30) after the operation, VAS levels were high already preoperatively and remained such (Table 1b). Although chronic post-surgery pain has probably a multifactorial origin, this seemingly patient related find merits further research. If pain does not subside by hernia repair, it may be that in these patients a significant portion of it arises from other conditions. Sensitivity to pain also varies. A noteworthy observation is that pain VAS level in the groin while resting in 12% of patients was significantly higher at follow-up than before operation (Table 1c). Most of these patients started out with markedly low VAS values (7) often interpreted as “no pain” in cut off points and ended in “mild pain” (20) after repair.

Similar to here, association between higher preoperative groin pain levels and chronic postoperative pain has been noted earlier. Four questionnaire surveys with miscellaneous operation techniques revealed that patients who retrospectively recalled higher preoperative pain levels had higher chance for chronic postoperative pain [5,18–20]. Two prospective studies (n = 150–300)

Table 1c
Higher VAS level at operation site at follow-up compared to the preoperative level, complete answers (n = 675).

	VAS increase (n = 80)	VAS decrease or stationary (n = 595)
Percent	11.9	88.1
Preoperative VAS, resting	7 (13)	30 (25)
Postoperative VAS, resting	20 (23)	4 (12)
VAS difference	+13 (18)	−26 (24)
P[a]	**<0.001**	**<0.001**

Values are mean (standard deviation).
[a] Wilcoxon signed rank test.

Table 2
Multivariate binomial logistic regression analysis for independent predictors of chronic pain (not present vs. present) at one year after open hernia repair, one step, n = 706 hernias, 698 patients.

Variable	Descriptive measure	Odds ratio	Confidence interval (95%)	*P*
Chronic pain	93 (13.2)			
Complication vs. no complication	22 (3.1)	5.16	1.84–14.47	**0.002**
Recurrence vs. non-recurrence	10 (1.4)	6.77	1.78–25.73	**0.005**
VAS preoperatively	2.7 (2.5)[a]	1.15	1.04–1.26	**0.006**
Age (years)	56 (17–88)[b]	0.98	0.97–0.99	**0.027**
Mesh type				**0.037**
Lightweight, 35–50 g/cm^2	311 (44.0)		Reference	
Mid-weight, 50–80 g/cm^2	345 (48.9)	2.28	1.20–4.36	**0.012**
Heavyweight, >80 g/cm^2	50 (7.1)			0.547
Hernia type				0.082
Combined	49 (7.6)		Reference	
Lateral	407 (57.6)			0.131
Medial	241 (37.2)			0.038
Recurrent	9 (1.3)			0.383
BMI (kg/m^2)	24.7 (17–40.9)[b]			0.232
Duration of operation (min)	33 (15–100)[b]			0.409
Anesthesia form				0.105
Regional	90 (12.7)		Reference	
Local	598 (84.7)	0.46	0.21–1.01	0.053
General	18 (2.5)			0.913
Male sex vs. female sex	646:52[c]			0.968

Values are counts (percent).
[a] Mean (standard deviation).
[b] Median (range).
[c] Males:females.

Table 3
Predictors for Visual Analogue Scale score 1–4 years after herniorrhaphy in linear regression, one step. Positive coefficient means predictor for higher VAS, n = 648 hernias, 642 patients.

Variable	Descriptive measure	Regression coefficient	Confidence interval (95%)	*P*
Postoperative VAS	0.7 (1.5)[a]			
Preoperative VAS	2.8 (2.5)[a]	0.10	0.05–0.15	**<0.001**
Recurrence vs. no recurrence	10 (1.5)	1.49	0.61–2.38	**0.001**
Complication vs. no complication	21 (3.2)	0.76	0.14–1.38	**0.016**
Mesh type				
Lightweight, 35–50 g/cm^2	255 (39.4)		Reference	
Mid-weight, 50–80 g/cm^2	343 (52.9)			0.293
Heavyweight, > 80 g/cm^2	50 (7.7)	0.50	0.01–0.99	**0.046**
Anesthesia type				
Regional anesthesia	67 (10.3)		Reference	
Local anesthesia	576 (88.9)			0.412
General anesthesia	5 (0.8)	2.83	2.12–4.64	**<0.001**
Male sex vs. female sex	593:49[b]			0.377
Age (years)	57 (17–88)[c]			0.106
Hernia type				
Combined	42 (6.5)		Reference	
Lateral	373 (57.6)			0.581
Medial	224 (34.6)			0.216
Recurrent	9 (1.4)			0.664
Duration of operation (min)	33 (15–100)[c]			0.957
BMI (kg/m^2)	24.6 (17–41)[c]			0.516
Time to follow-up point (month)	12 (12–46)[c]			0.960

Values are counts (percent).
[a] Mean (standard deviation).
[b] Male:female.
[c] Median (range).

with varying surgery techniques found a positive correlation between higher preoperative VAS scores and chronic postoperative pain [21,22]. Improvement of pain management of inguinal hernia before operation has been advocated but not examined [23]. Effects of preemptive pain medication on chronic post-surgery pain have been inconclusive too. Oral gabapentin an hour before inguinal hernia repair ($n = 59$) lowers Numerical Rating Scale (NRS) scores for groin pain at 6 months but not the share of patients with adverse pain [24]. If reducing preoperative VAS scores pharmacologically has an effect on chronic postherniorrhaphy pain could be part of future research.

Age at operation was found to be an independent predictor of chronic postherniorrhaphy pain in the present study: each year of advancing age decreased the risk by approximately 2%. This find is in accordance with previous retrospective surveys and a registry study and noted by the European Hernia society [18,21,25,26]. An explanation may be decreased sensory function as demonstrated by heat stimulus tests among elderly [27]. Reduced risk of chronic postherniorrhaphy pain is a factor supporting operative treatment among elderly especially since their quality of life gains are similar to younger patients' [28].

Whether and which implant characteristics produce more adverse effects in hernia surgery has been discussed since the onset of tension-free repairs. One trend has been to reduce the amount of implanted material as much as feasible. Support of this comes from individual trials and meta-analyses [29–31]. In the present study, chances of chronic pain or higher VAS scores were increased by heavier weight mesh types compared to lightweight meshes. That heavyweight meshes were associated with higher postoperative VAS levels seems understandable. Why they were not associated with chronic pain like mid-weight meshes is harder to explain. This may have to do with the definition of chronic pain in this study and the relative numbers of mesh types and weight cut off points. Role of mesh attachment with respect to pain has also been a center of interest. Disturbance of sensory nerves by penetrative fixation methods is suspected [32]. Here, mesh weight and attachment method categories showed covariance. When mesh attachment was dichotomized into penetrative and non-penetrative types and added in the logistic regression model mesh weight lost statistical significance slightly ($P = 0.057$) but other model results remained essentially the same. Mesh attachment type itself remained statistically insignificant. This would imply that in this study mesh weight carried more significance to chronic pain than attachment method.

Hernia type was found not to be associated with chronic pain in the present study. Contrastingly, an earlier survey applying regression analysis identified medial hernia as a risk factor for functional impairment in the postherniorrhaphy patient [5].

Here, complications lead to an increased chance of chronic postherniorrphaphy pain which is in line with retrospective surveys [5,18]. Low counts of individual complication types necessitated their summation in this study. Wide confidence intervals in Odds ratios advice cautious interpretation concerning how high exactly the risk is. If the relative risk regarding individual complication types could be determined more precisely, re-evaluation of e.g. antibiotic prophylaxis might be implicated from the point of view of chronic pain in places where infection rates are higher. That recurrence of inguinal hernia is associated with chronic groin pain seems logical.

This study did not repeat earlier results indicating that the chance of postherniorrhaphy pain declines with passing time [2]. Neither was operation on recurrent hernia found to be a significant risk for chronic postherniorrhaphy pain contrary to earlier findings drawn from miscellaneous operation techniques [19,33]. Sex and BMI had no effect on chronic postherniorrhaphy pain here similarly to earlier surveys and trials [5,18,27]. General anesthesia predicted higher postoperative VAS levels compared to regional anesthesia but due to the low number of cases this result should be interpreted with care. General anesthesia may have correlated with larger hernias or more sensitive patients. Removing anesthesia types completely from the linear regression model did not have an effect on the overall results. Both insignificant and significant association of anesthesia method with postherniorrhaphy pain has been reported [2,20].

Although the overall patient attendance was relatively high only about 70% of potentially obtainable data could be used in the analyses which is one of the disadvantages of this study (Fig. 1). However, the circa 15% of non-analyzable data apart from non-response (circa 15%) was rather random in nature: patient forgetting to provide identification, leaving empty or unclear answers in the questionnaires or staff forgetting to record trial related data. No unreasonable bias should result from such missing information. Included here were patients who entered studies 1 and 2 with bilateral hernias producing discrepancy between hernia and patient numbers. A potential source for distortion in the results may be considered the fact that pain VAS scores were obtained either during a visit to the hospital or at home. However, both are essentially instances of self-administration of a pain measurement tool with paper and pencil. A postal questionnaire was considered a justifiable means to test whether passing time affects pain as previously noted. Validation of postal questionnaires for hernia outcome has shown adequate correlation [34]. Visual analogue scale has been deemed rather abstract. Furthermore, hernia patients are often elderly and may have compromised eyesight. VAS was supplemented with questions. As the majority of inguinal hernias are treated according to the tension-free concept, the results of this study can be generalized to the typical inguinal hernia patient.

Finding risks for postherniorrhaphy pain affects treatment strategies, implant materials, operative techniques and allows for preventive measures. One difficulty in this approach is the demand for a large number of patients. Here the prospectively collected details from several operations with similar design conducted under the uniform Finnish public health care were analyzed. This study reinforces the finding that older patients do well with open mesh placement in terms of risk for chronic pain. The results suggest that particularly painful inguinal hernia patients be examined carefully preoperatively. Patients who present with very mild pain should be informed of the chance for more pain after inguinal hernia repair. Hemostasis and prevention of infection should be meticulous to produce as few complications as possible.

5. Conclusions

Complication, hernia recurrence, mesh weight, preoperative VAS score and age are predictors for chronic pain after open mesh based inguinal hernia repair or postoperative VAS levels.

Conflicts of interest

None.

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A statistician's consultation was paid from Helsinki University Hospital Fund. The fund had no involvement in study design; in the collection, analysis and interpretation of data; in the writing of the report; or in the decision to submit the article for publication.

Ethical approval

The RCTs on which this work bases were approved by the local hospital ethics committees. This is stated in the methods section of the manuscript.

Author contribution

Georgios Pierides: conception of the study, analysis and interpretation of data, drafting the article and revising it critically for important intellectual content, final approval of the version to be submitted.

Hannu Paajanen: conception and design of the study, acquisition of data, revising the manuscript critically for important intellectual content, final approval of the version to be submitted.

Jaana Vironen: the conception and design of the study, analysis and interpretation of data, revising the manuscript critically for important intellectual content, final approval of the version to be submitted.

Guarantor

Georgios Pierides.
Jaana Vironen.

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