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Original Research

Periumbilical vs transumbilical laparoscopic incision: A patients' satisfaction-centered randomised trial



Audrey Bouffard-Cloutier, Alex Paré, Nathalie McFadden*

Department of Surgery, Division of General Surgery, Université de Sherbrooke, Sherbrooke, Quebec, Canada

HIGHLIGHTS

- PUI and TUI lead to similar clinical outcomes and patient cosmetic satisfaction.
- 72% of patients confer very little attention to the appearance of the umbilicus.
- Patients valuing the appearance are at risk of lowered postoperative satisfaction.

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ABSTRACT

Background: While studies suggested that transumbilical incisions (TUI) incur better postoperative cosmetic satisfaction scores (CSS) and shorter operative time (OT) than periumbilical incisions (PUI) during general surgery laparoscopic interventions, others did not. Concerns have been raised toward the potential negative impact of TUI on the incidence of surgical site infection (SSI) but this issue is under documented.

Methods: A controlled trial was conducted between August 2014 and August 2015 in our hospital. Individuals aged 18–70 undergoing a laparoscopic rectopexy, cholecystectomy, appendectomy or proctocolectomy were considered. Patients were randomized in two groups (PUI or TUI) following a 1:1 allocation ratio. Participants with a body mass index >40, with a history of abdominal surgery, undergoing co-operations, requesting a specific incision or converted to open surgery were excluded.

Results: Among the 56 randomized patients, 50 (27 PUI vs 23 PUI) produced analyzable data.

There were no significant difference between the characteristics of both groups. CSS evolution (pre-op vs 1 month post-op), SSI incidence and OT were also comparable. Only 28% of participants valued the appearance of their umbilicus prior to intervention. Those who did had a significantly worst CSS evolution (OR -1.7; IC95-2.6/-0.72, p = 0.001). Higher preoperative CSS was also a predictor of postoperative CSS decline (OR -0.4; IC95-0.6/-0.2, p = 0.001).

Conclusions: SUI and TUI were similar for all tested outcomes. Among the participants, the minority of patients who valued the appearance of their umbilicus and those with a high preoperative CSS were particularly prone to postoperative CSS decline.

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1. Introduction

In the field of general surgery, laparoscopic interventions require the creation of a pneumoperitoneum to allow the initial peritoneal access. In order to insert the laparoscope, a transumbilical (TUI) or periumbilical incision (PUI) is usually

E-mail address: nathalie.mcfadden@usherbrooke.ca (N. McFadden).

performed. PUI is U-shaped, located above (supraumbilical) or below (infraumbilical) the umbilicus and cuts through the skin, the subcutaneous fat and the fascia. TUI is vertical, located inside the umbilical ring and cuts through the skin and fascia [1]. While no systematic review/meta-analysis has yet assessed the clinical equivalence of both incisions, the vast majority (>85%) of Canadian general surgeons prefer PUI over TUI during their laparoscopic interventions [2]. This national practice pattern is intriguing since Asian surgeons seem to rather consider TUI as the standard laparoscopic incision [1,3,4].

An advocated advantage of TUI is the absence of an apparent

^{*} Corresponding author. Centre Hospitalier Universitaire de Sherbrooke- Hotel-Dieu, Division of General Surgery, 580, rue Bowen Sud, Sherbrooke, Quebec, J1G 2EB, Canada.

scar (hidden within the umbilicus). This could lead to an increased patient's postoperative cosmetic satisfaction. In this regard, a 2016 randomized trial suggested a significantly higher postoperative BIQ score (Body Image Questionnaire) when a TUI was completed instead of a PUI (36.8 \pm 5.2 vs 33.2 \pm 5.2,P < 0.001) during standard laparoscopic cholecystectomies [3]. While this result is promising, no other research has yet compared TUI and PUI regarding patient's cosmetic satisfaction. No study has either assessed who much value patients are giving to the appearance of their umbilicus prior to this kind of intervention.

Another potential advantage of TUI is a shorter operative time (OT). Since TUI require less layers to be cut through and may be closed using a single full later suture [3], this hypothesis seems plausible. At the current time, a sole research did observed a significant reduction in OT when using TUI over PUI (34.2 \pm 14.6 vs 41.7 \pm 21.3, P = 0.020) [3]. Other studies found no such association [1,5,6].

Despite its possible advantages, TUI utilization seems to remain quite limited in Canada. Some concerns have been raised toward the potential negative impact of TUI on the rate of surgical site infection (SSI). Since the umbilicus is prone to microbacterial colonization (humid environment + large number of resident bacterias) [7,8], its avoidance (by performing a PUI instead of a TUI) could be beneficial to reduce SSI. This hypothesis has been reinforced by studies who confirmed that even a deep antiseptic umbilicus skin preparation fails to eradicate resident bacterias in about 20-25% of cases [8,9]. While one research did observed a significant reduction of SSI by switching from TUI to PUI (23.6% vs 11.6%, p=0.01) [11], other studies found no such association [1,3,5,10].

The current literature provides limited and contradictory information about TUI and PUI. The primary objective of this study is to assess the impact of both incisions on patients' postoperative cosmetic satisfaction, rate of SSI and operative time. As secondary objectives, we aim to evaluate the proportion of participants giving value to the appearance of their umbilicus and to evaluate the predictors of cosmetic satisfaction score variation and umbilicus appearance consideration.

2. Materials and methods

2.1. Trial design

A randomized controlled trial was conducted between August 22th 2014 and August 20th, 2015 in this hospital. Patients were randomized in two groups ("PUI incision" vs "TUI incision") following an allocation ratio of 1:1. The trial was registered (NCT03026400) and approved by the ethics committee. There were no changes to methods after trial initiation.

2.2. Participants

Patients aged 18—70 undergoing a laparoscopic rectopexy, cholecystectomy, appendectomy or proctocolectomy were approached before the intervention. Patients with a BMI >40, those with a history of abdominal surgery involving the umbilicus, individuals undergoing co-operations, patients specifically requesting PUI or TUI and those converted from laparoscopic to open surgery were excluded.

2.3. Interventions

Patients randomized in the TUI group were exposed to the following standardized technique: after general anesthesia, umbilicus cleaning (cotton swabs + alcohol) and skin preparation (chlorhexidine), the umbilicus was inverted using graspers. A

vertical incision extending through the full length of the umbilical ring was performed at the bottom of the umbilicus to reach the physiological hernia and enlarge it to allow a 10 mm port placement. The Hasson technique was used for pneumoperitoneum creation. The conduct of the rest of the surgery was left to the surgeon's preference. X-stitches were used for closure. Patients randomized in the PUI group were exposed to the same standardized technique but a 10–15 mm curvilinear horizontal incision was completed instead of a TUI. The aponeurosis or physiologic hernia space was incised with a scalpel and the peritoneal layers were open using a Kelly clamp. The Hasson technique was followed for pneumoperitoneum creation and X-stitches were used for closure. All randomized patient received the allocated intervention. All patients received one dose of antibiotic intravenously at induction (piperacillin/tazobactam).

2.4. Randomization and intervention assignment

Before trial initiation, A.Bouffard-Cloutier used a random number table (computer-generated) to identify 80 sealed envelopes (40 PUI/40 TUI) containing a randomization sheet (8.5 \times 5.5 white sheet with the word "TUI" or "PUI"). The envelopes where stored in identified OR cabinets. Following patient's written consent (obtained by all authors), a signaling sheet was added to surgery protocol. This sheet notified the attending surgeon of patient's recruitment and contained useful information regarding study conduct (notably the location of the randomization envelopes). When a participant arrived in OR, the attending surgeon had to pick a numbered sealed envelope, check the assignment group and perform the indicated incision. Following intervention, the surgeon had to send the patient's envelope (containing the consent form, signaling and randomization sheet) back to A.Paré by intern mail. Due to the visible nature of tested interventions and direct implication of all authors in randomization and data collection, no blinding was performed.

2.5. Outcome measurement

Patient's cosmetic satisfaction score (CSS), incidence of surgical site infection (SSI) and operative time were the primary outcomes. Value given by patients to the aesthetic appearance of the umbilicus (yes/no) was the secondary outcome. CSS was evaluated using an inverted 10 points facial grimace-type scale. Zero out of ten was the lowest CSS while 10 was the highest. This outcome was recorded after the signature of the consent form (prior the surgery), 30 days post-op and 180 days post-op. Preoperative CSS was extracted from a self-completed paper form questionnaire. Thirty and 180 days post-op data collection was done using a direct telephonic follow-up interview (A.Paré). CSS evolution was calculated between each observation time. The incidence of SSI was assessed by reviewing the 4-6 week-post-op attending surgeon's evolution notes (in the electronic medical record). Operative time (OT) was also extracted from patient's electronic medical record. The value given to the aesthetic appearance of the umbilicus was assessed preoperatively by the attending surgeon. The following standardized question was used: "Do you value the aesthetic appearance of your umbilicus?". The possible answers were restricted to "Yes/ Somehow" or "No/Very little" and indicated in a baseline questionnaire. In addition to those outcomes, patient's age, sex, body mass index (BMI), tobacco consumption, education level, type and setting of surgery and depth of the umbilicus were collected from the medical record and baseline questionnaire.

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