



Trabajo Original

Performance of outpatient total laparoscopic hysterectomy on transsexual patients. Satisfaction and economic impact

Realización de histerectomía laparoscópica total ambulatoria en pacientes transexuales. Satisfacción e impacto económico

Laura Ces Silva¹, Marta Coloma Escribano¹, Delia Rosa Báez Quintana², Margarita Álvarez de la Rosa Rodríguez², Miguel Ramón Carrancho Montero¹, Antonio Gil-Moreno³

¹Department of Obstetrics and Gynecology. Complejo Hospitalario Universitario de Canarias. La Laguna. Tenerife. ²Department of Obstetrics and Gynecology. Complejo Hospitalario Universitario de Canarias. Universidad de La Laguna (ULL). La Laguna. Tenerife. ³Unit of Gynecologic Oncology. Department of Obstetrics and Gynecology. Hospital Universitari Vall d'Hebron. Vall d'Hebron Barcelona Hospital Campus. Universitat Autònoma de Barcelona. Barcelona

Abstract

Objective: To assess the safety, satisfaction and economic impact of total laparoscopic hysterectomy with bilateral salpingo-oophorectomy performed as an outpatient procedure on transsexual patients.

Material and methods: Retrospective cohort study conducted in a tertiary university hospital, between 2015-2018. Epidemiological data, intraoperative and postoperative complications and surgical results were collected. Pain score, general state of health and satisfaction levels were assessed on a phone survey. Cost savings were calculated taking as a reference the average cost of stay.

Results: 49 patients were recruited. Admission was required in two cases (4.1%). The rate of intraoperative complications was 6.1% (3/49) and there were no major complications. Six patients (12.2%) attended the emergency services but no admission were required. 97.6% (41/42) of patients was regarded their general state of health as good or excellent and the average pain score was 2.20 according to the Visual Analogue Scale. Calculated cost savings based on the outpatient procedure were €45,705.62.

Conclusions: The performance of total laparoscopic hysterectomy with bilateral salpingo-oophorectomy as an outpatient procedure on transsexual patients presents minor complications, a low rate of readmission and emergency visits, high patient satisfaction levels and low pain scores, with reduced costs.

Resumen

Objetivo: evaluar la seguridad, satisfacción y el impacto económico de la histerectomía total laparoscópica con salpingo-oooforectomía bilateral realizada como un procedimiento ambulatorio en pacientes transexuales.

Material y métodos: estudio de cohorte retrospectivo realizado en un hospital universitario de tercer nivel, entre 2015-2018. Se recogieron datos epidemiológicos, complicaciones intraoperatorias y postoperatorias y resultados quirúrgicos. La puntuación de nivel de dolor, el estado general de salud y los niveles de satisfacción se evaluaron mediante encuesta telefónica. El ahorro económico se calculó tomando como referencia el coste por estancia hospitalaria.

Resultados: se recogieron 49 pacientes. El ingreso hospitalario fue necesario en dos casos (4,1%). La tasa de complicaciones intraoperatorias fue del 6,1% (3/49) y no hubo complicaciones mayores. Seis pacientes (12,2%) acudieron al servicio de urgencias, pero no precisaron ingreso. El 97,6% (41/42) de los pacientes consideraron su estado de salud general como bueno o excelente y la puntuación promedio de dolor fue de 2,20 según la escala visual analógica. El ahorro de los costes calculados basados en el procedimiento ambulatorio fue de 45.705,62€.

Conclusiones: la histerectomía total laparoscópica con salpingo-oooforectomía bilateral como procedimiento ambulatorio en pacientes transexuales presenta complicaciones menores, una baja tasa de reingresos y consultas al servicio de urgencias, altos niveles de satisfacción del paciente y bajos niveles de dolor postquirúrgico, con un ahorro económico añadido.

Key words:

Hysterectomy.
Laparoscopic hysterectomy.
Transsexualism.
Ambulatory surgical procedure.
Transgender persons.

Palabras clave:

Histerectomía.
Histerectomía laparoscópica.
Transexualidad.
Procedimiento ambulatorio.
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Correspondencia:

Laura Ces Silva
Department of Obstetrics and Gynecology
Complejo Hospitalario Universitario de Canarias
Universidad de La Laguna
Ctra. Ofra s/n La Cuesta. 38320 La Laguna. Santa Cruz de Tenerife
e-mail: lauracesilva@gmail.com

INTRODUCTION

Gender dysphoria is a condition caused by incongruence between an individual’s biological sex and their gender identity (1). When it comes to gender dysphoria management, the performance of total hysterectomy with bilateral salpingo-oophorectomy (BSO) is regarded as a valid therapeutic option according to the standards set by the World Professional Association for Transgender Health (WPATH) (2). For surgical treatment involving hysterectomy with BSO, a referral from two qualified mental health professionals is required to be issued in accordance with criteria determined by ICD-10 (3) and in full compliance with the criteria set by the WPATH (Table I).

Many authors consider transgender men as ideal candidates to benefit from the safety and effectiveness of total laparoscopic hysterectomy with bilateral salpingo-oophorectomy (TLH+BSO) (4-7).

Several retrospective observational studies have shown that total laparoscopic hysterectomy (TLH) as outpatient surgery is safe (8,9), more cost-effective and implies similar readmission rates when compared to an inpatient procedure (10,11), especially if adequate surgical planning and careful patient selection are guaranteed (12). Ambulatorization is particularly relevant when it comes to the transgender male as the emotional distress triggered by gynecological admission is eliminated and patient satisfaction levels could be increased. However, there is limited literature available regarding the performance of ambulatory TLH+BSO on female-to-male transsexuals (13).

We have found no studies focusing on the analysis of satisfaction levels, pain scores or the associated economic impact of transsexual patients when subjected to ambulatory TLH+BSO. Our objective is to determine the viability of the performance of ambulatory TLH+BSO on male transsexuals in terms of complications, safety, economic impact and patient satisfaction.

Tabla I.

Criteria WPATH for hysterectomy and salpingo-oophorectomy in transsexual’s patients (2)

| | |
|----|---|
| 1. | Persistent, well documented gender dysphoria |
| 2. | Capacity to make a fully informed decision and to consent for treatment |
| 3. | Age of majority in a given country |
| 4. | If significant medical or mental health concerns are present, they must be well controlled |
| 5. | 12 continuous months of hormone therapy as appropriate to the patient’s gender goals (unless the patient has a medical contraindication or is otherwise unable or unwilling to take hormones) |

Abbreviations: WPATH, World Professional Association for Transgender Health.

MATERIAL AND METHODS

Patients

We performed a retrospective cohort study of transsexual patients who underwent TLH+BSO at the University Hospital of the Canary Islands between April 2015 and February 2018. Our Hospital is a tertiary referral center for a population of 1,020,490 inhabitants. This study received ethics approval from the local Committee. Written and oral informed consent was obtained for surgery.

Patients were selected by the same senior consultant on the preoperative phase by following the inclusion-exclusion criteria listed in table II.

Tabla II.

Inclusion-exclusion criteria

| | Inclusion criteria | Exclusion criteria |
|-------------------|---|---|
| Surgical criteria | <ul style="list-style-type: none"> • Presumed benign disease • Normal or slightly enlarged uterus by ultrasound evaluation | <ul style="list-style-type: none"> • Anticipated surgical complications • Contraindication to endoscopic surgery |
| Medical criteria | <ul style="list-style-type: none"> • ASA score ≤ 2 | <ul style="list-style-type: none"> • ASA score > 2 • Morbid Obesity (BMI > 40) and serious cardiorespiratory disease that prevents the position of Trendelenburg |
| Social criteria | <ul style="list-style-type: none"> • Adequate motivation and understanding • Continuous home support for the first 2 days • Ability to follow medical instructions • Satisfactory hygiene and accommodation conditions • Convalescence at a location no further than 1 hour drive to hospital • Telephone accessible 24 hours a day | <ul style="list-style-type: none"> • Inability to understand and follow oral and written instructions about the procedure • Psychiatric disease that prevents collaboration |

Viability was defined as the successful performance of TLH+BSO without major hemorrhage or visceral injuries. Safety was determined by considering the following variables: Unscheduled postoperative readmissions, medical consultation or complications within 3 months after surgery and postoperative pain scores within 24 hours after surgery. Patient satisfaction was measured by considering the general state of health described by patients themselves 24 hours after the surgery. To analyze the economic impact of the outpatient versus inpatient procedure we took as reference the average cost of stay of gynecological admissions at our Center provided by the Finances Department of the Hospital: €972.46/day.

Surgical technique

Surgery was performed under general anesthesia. The use of an adjustable uterine manipulator (Advincula ArchTM, CooperSurgical, Trumbull, CT) allowed optimal uterine mobilization. Levobupivacaine 0.25% was injected at the port sites as a routine procedure before incision, and the number and size were appropriately noted in the medical record. The vaginal vault was closed by laparoscopic continuous unidirectional barbed suture (STRATAFIX®, monofilament 0, Ethicon, Johnson & Johnson). After completion of surgery, each patient received intraperitoneal instillation of 20 ml of 0.25% levobupivacaine. Operating time was defined as the time that elapsed between incision and complete closure. The urinary catheter was removed after a maximum of four hours and oral intake was initiated between 4-6 hours after the procedure.

The patient remained under observation for a minimum period of 6 hours following surgery. Criteria for the safe discharge of patients were established as follows: Adequate pain control with oral analgesia, food tolerance without significant nausea, ability to mobilize, spontaneous micturition and absence of significant bleeding. At hospital discharge, oral medication consisted of 1g paracetamol/6 hours and additional analgesia based on 25 mg dexketoprofen/8 hours in case of pain, 20 mg omeprazole daily and 40 mg subcutaneous enoxaparin daily for 10 days.

Patients were scheduled for a medical visit 4 weeks after surgery. They were informed about postsurgical care and activities, and about warning signs that required an immediate call to the emergency services. A written document containing these recommendations was also handed. The number of outpatients was recorded and if the patient caused admission, the reason and length of stay were registered. Unscheduled visits to the emergency services, complications and readmissions within 3 months after surgery were also recorded. Surgical and postoperative complications were graded as minor or major according to the Clavien-Dindo classification (14).

A nurse contacted each patient by phone 24 hours after the procedure to conduct a postoperative survey. Patients admitted as inpatients were excluded from the survey. Questions focused on: Patient general state of health (graded as bad, medium, good or excellent); pain assessment according to a Visual Analogue Scale (VAS) from 0-10 (no pain to unbearable pain); nausea, vomit and/or fever; intake of scheduled analgesics, need and effectiveness of rescue analgesic use. The Finance Department of the hospital estimated the average cost of stay of gynecological admissions at €972.46 during the time frame of the study, which was taken as a reference to calculate cost savings associated with each patient discharge after the procedure.

Statistical analysis

SPSS (IBM Corp. Released 2013. IBM SPSS Statistics for Windows, Version 21.0. Armonk, NY: IBM Corp.) was used for data analysis of this study. Mean and 95% confidence intervals were considered for continuous variables while relative frequencies and percentages were applied for categorical variables. The analysis of variance (ANOVA) was carried out to compare average values of pain scores between groups and the non-parametric Spearman's rank correlation was applied to compare pain scores and surgical time. Statistical relevance was established at $P < 0.05$.

RESULTS

During the time period our study, a total of 49 transsexual patients were recruited for the performance of TLH+BSO as outpatient surgery. One of the patients was excluded due to the non-fulfillment of criteria for outpatient surgery due to obesity.

The mean age of patients was 25.7 years (95% CI 23.38-27.98) and the mean BMI was 25.1 kg/m² (95% CI 23.53-26.69). The mean operating time was 96 minutes (95% CI 88.16-105.11) and the overall rate of complications was 18.3% (9/47). Patient characteristics and perioperative variables are listed in tables III and IV.

95.96% of patients (47/49) were discharged on the same day of the surgery, while 2 patients (4.1%) were admitted as inpatients due to hymenal ring laceration, which required suture, in one case, and late completion of surgery (after 6 p.m.) in the other. Both patients were discharged one day after surgery.

When it comes to perioperative results, no patient required conversion to open laparotomy. Three patients (6.1%) presented minor intraoperative complications, caused by vaginal bleeding, which was treated with partial suturing of the hymenal ring laceration (none had previous vaginal intercourse).

Tabla III.
Patient characteristics^a

| Characteristics | Values (mean, 95% IC) |
|---------------------------------|---|
| Age (years) | 25.7 (95% IC 23.38 - 27.98) |
| BMI (kg/m ²) | 25.1 kg/m ² (95% IC 23.53 - 26.69) |
| Values (n [%]) | |
| Parity | 0 |
| Previous abdominal surgery | 2 (4.1%) |
| No previous vaginal intercourse | 17 (34.7%) |

Abbreviations: BMI, body mass index; kg, kilogram; m², square meter; IC, confidence interval. ^aValues are given as mean (95% confidence interval) or number (percentage).

Tabla IV.
Perioperative characteristics^a

| Perioperative characteristics | Values (mean, 95% IC or n [%]) |
|--|--|
| Port laparoscopic technique (ports sizes) | |
| 3 ports (5-5-5 mm) | 45 (91.8%) |
| 3 ports (5-5-11 mm) | 3 (6.1%) |
| 4 ports (5-5-5-12 mm) | 1 (2%) |
| Port site infiltration (pre-surgical) | 49 (100%) |
| Intraperitoneal instillation (post-surgical) | 49 (100%) |
| Surgical time (min) | 96 min (95% IC 88.16 - 105.11) |
| Adhesions | 0 |
| Intraoperative complications | 3 (6.1%) |
| Postoperative complications (≤ 30 days post-surgery) | Postoperative complications (≤ 30 days post-surgery) |

Abbreviations: IC, confidence interval; min, minutes; mm, millimeter. ^aValues are given as mean (95% confidence interval) or number (percentage).

Six patients (12.2%) visited the emergency services within 15 days; there were five cases of vaginal bleeding, which needed to be cauterized with silver nitrate or temporary tamponade, and 1 case of infected vaginal cuff, which was treated with oral antibiotics for 7 days. None of these patients needed to be admitted as inpatient (Table IV).

The phone survey response rate conducted within 24 hours after surgery was 85.7% (42/47); 97.6% (41/42) of them regarded their general state of health as good or excellent. No cases of fever, nausea or vomit were reported (Table V). Pain quantified by VAS was not related to the number or size of the ports (ANOVA p=0.62) nor to operating time (Spearman correlation p = 0.609).

Tabla V.
Postoperative survey^a

| Postoperative survey | N = 42 (83.7%) |
|---|--------------------|
| Overall status (n, %) | |
| Bad | 0 (0%) |
| Regular | 1 (2.4%) |
| Good | 34 (81%) |
| Excellent | 7 (16.7%) |
| VAS score (mean, 95% IC) | 2.20 (1.45 - 2.94) |
| Absence of nausea, vomiting and/or fever (n, %) | 42 (100%) |
| Took patented analgesia (n, %) | 42 (100%) |
| Required rescue analgesia (n, %) | 21 (50%) |
| Pain decreased (n, %) | |
| Yes | 39 (92.9%) |
| No | 3 (7.1%) |

Abbreviations: VAS, visual analog scale; IC, confidence interval. ^aValues are given as mean (95% confidence interval) or number (percentage).

The 47 patients who were not admitted as inpatients led cost savings to be estimated at €45,705.62, considering a hospital stay of one day equivalent to €932.76 per patient.

DISCUSSION

Not only is TLH+BSO safe and viable to be performed on transsexual patients as an outpatient procedure but it also shows high patient satisfaction levels and involves significant cost savings.

Following the standards of care set by the WPATH, TLH+BSO is considered as an integral part of the gender affirmation process (2). Although most hysterectomy procedures available to be performed on transsexual patients are described in medical literature, there is major debate and discussion when it comes to the vaginal and laparoscopic approaches. Both was regarded as minimally invasive surgery (15) but while some authors state that the former is not dependent on vaginal conditions or parity (16,17), others argue that the latter provides an enhanced view of tissues and hemorrhage control (4-7). In any case, no particular procedure has been yet determined as the only course of action in these cases and latest research shows that both approaches are equally safe and associated with comparable rates of complications (18). In our study, the laparoscopic approach was adopted since we counted on the expertise of laparoscopic surgeons and was considered as the best option for access in BSO performance due to the fact that our sample consisted of 100% nulliparous patients and 34.7% reported having never had vaginal intercourse.

The performance of both vaginal and laparoscopic methods as outpatient surgery is a safe option and it is

becoming increasingly common (10), counting on just one published review of case studies of laparoscopic hysterectomy performed on transsexual patients with same-day discharge (13).

As only 2 patients were admitted as inpatients, the rate of outpatient surgery reached 85.7%, which proved significantly higher when compared to the review conducted in 2012, in which the performance of ambulatory TLH only amounted to 26.5% (11). There might be a direct correlation between the high rate of outpatient surgery and the optimal clinical characteristics of our population group, made up of young and pathology-free patients. Over recent years, we are witnessing the increasing performance of numerous surgical procedures as outpatient surgery, which is contributing to the consolidation of Outpatient Major Surgery Unit. In addition, although all patients may benefit from outpatient surgery, it is especially advantageous for the transsexual population when it comes to lower emotional distress, as gynecological admission is not required, and the likely improvement of other commonly associated complications, such as steroid-induced thromboembolism.

Table VI provides an overview of minor and major intraoperative complications published in previous studies on transsexual patients subjected to TLH+BSO, in which low rates of intraoperative complications can be observed, mainly due to minor complications. In our study, no major complications were registered and minor intraoperative complications reached a rate of 6.1% (3/49). Our rate of complications is lower than that reported by Bogliolo (10%) (4) and Marfori (8.3%) (13), which also showed the same minor complication: Hymenal ring laceration. It is, however, higher than that published by Weyers (7), of 2.4% and by O'Hanlan (6), of 4.9%, although both included major complications (perforation of the bladder and conversion to laparotomy), so they are not comparable with the results of our study where they were all minor complications.

In our study, there was no need for readmission, in accordance with latest published literature (table VI).

Postoperative complications were assessed based on unscheduled visits to the emergency services. The percentage of visits was reported to be reasonably low (12.2%), due to minor complications in all cases. Our results are similar to some reported in other case studies (5,6) and lower to some others, although with more modest values (13). However, they prove to be higher than those of Weyers (4.8%). But in this study (7) the length of stay was 5 days and the period of data collection of postoperative complication is not specified.

In our study, VAS pain score 24 hours after surgery was 2.2, similar to that of 1.8 by Donnez (19) and significantly lower than the one by Gauta of 4.8 (20). This might be due to the fact that, in Gauta's work, almost 30% of patients presented adhesions caused by endometriosis, likely to be associated with the perception of higher

pain scores. Despite available evidence that port-specific pain is mainly dependent on incision size and distribution (21), no significant differences were observed in our study regarding the number and size of ports used. It might be associated with the low number of cases (4/49) in which trocars other than 5-5-5 mm were utilized. Numerous studies have shown both the benefits of infiltration at port sites to reduce postoperative pain and that of peritoneal instillation in laparoscopic gynecological surgery (22,23). As each of our patients was subjected to both techniques, potential differences in VAS pain scores cannot be assessed. It seems reasonably safe to state, however, that both of them are beneficial.

After reviewing published studies that focus on patient satisfaction following TLH performed as outpatient surgery (10), none of them has been found to target transgender patients. High patient satisfaction levels are reported (90-97%), but they are lower than the values recorded in our study, which amount to 97.6%. Although, in our series, the number of cases is limited and patient satisfaction is measured differently in each particular study, high patient satisfaction levels are particularly relevant after the performance of TLH+BSO as outpatient surgery on transgender patients, mainly because of the emotional and personal circumstances associated with this patient profile.

Outpatient Major Surgery Units provide cost reductions associated with each procedure as inpatient admission is not required, which leads to the increased cost-effectiveness and sustainability of our public health system. Cost savings in the framework of our series were estimated at €45,705.62, taking as a reference one hypothetical overnight stay in our hospital. In the study by Schiavone (11), the rates of surgical procedures performed as outpatient surgery show a progressive increase over the years, ranging from 18.57% in the year 2000 to 39.81% in 2010. In the same study, 37.47% of patients required a day of overnight stay while 22.70% required two days of overnight stay. If we applied these percentages to our study and made the proper calculations, the costs associated with our case group would have amounted to €39,487.70.

The main limitation of this study lays in its retrospective nature, also in the sample size and in the errors inherent to the survey process (response bias). The strengths are that no patients were lost to follow up, the surgical technique was standardized, we had a high questionnaire response rate, and we analyzed the costs.

CONCLUSION

The performance of ambulatory TLH+BSO on transsexual patients is a safe option in our environment, given the associated low rates of complications and readmissions, high levels of patient satisfaction (97.6%), low postoperative pain scores and significant cost savings.

Tabla VI.
Laparoscopic hysterectomies in transsexuals: Review of literature^a

| Source | n | Intervention type | OT mean (min) | Complications n (%) | | Complications requiring reoperation n (%) | Hospital stay mean (days) | Readmission rates N (%) | Pain VAS score mean | Satisfaction | Follow-up mean (months) |
|-------------------------|----|--|---------------|--|--|---|---------------------------|-------------------------|---------------------|---|-------------------------|
| | | | | Intraoperative | Postoperative | | | | | | |
| Ergeneli 1999 (24) | 8 | Vagnectomy and LAVH | 140 | <ul style="list-style-type: none"> 1 (12.5%) 1 Bladder perforation 2 (4.9%) | <ul style="list-style-type: none"> 2 (25%) 2 Deep vein thrombosis | 0 | NA | NA | NA | NA | 9-30 (range) |
| O'Hanlan 2007 (6) | 41 | TLH and BSO and appendectomy | 74 | <ul style="list-style-type: none"> 1 immediate take-back to the operating room for suture of hymeneal ring laceration (reintervention) 1 conversion to open laparotomy | <ul style="list-style-type: none"> 5 (12.2%) 2 pelvic cellulitis 2 vaginal cuff bleeding 1 vaginal bleeding (reintervention) | 2 (4.9%) | 1.07 | NA | NA | NA | NA |
| Lazard 2013 (25) | 10 | Hysterectomy with BSO by single port access | 150 | 0 | 0 | 0 | 3 | NA | NA | NA | NA |
| Weyers 2008 (7) | 83 | TLH and BSO +/- mastectomy | 64 | <ul style="list-style-type: none"> 2 (2.4%) 2 Bladder perforation | <ul style="list-style-type: none"> 4 (4.81%) 1 hematoma of vaginal dome (reintervention) 2 Urinary tract infection 1 episode of fever | 1 (1.2%) | 5.7 | NA | NA | NA | NA |
| Bogliolo 2014 (4) | 10 | Robotic Single -Site Hysterectomy and BSO | 137 | <ul style="list-style-type: none"> 1 (10%) 1 vaginal bleeding required a partial vaginal suture for hymeneal ring | 0 | 0 | 2.4 | NA | NA | VAS score >8 (Only available for five patients) | 6 months |
| Gomes da Costa 2015 (5) | 23 | TLH+BSO and vaginectomy | 155 | 0 | <ul style="list-style-type: none"> 3 (13.04%) 1 hemoperitoneum second day (reintervention) 1 prolonged urinary retention 1 perineal hematoma one month after surgery | 1 (4.34%) | 2-3 days (range) | NA | NA | NA | NA |
| Marfori 2017 (13) | 12 | 2-port TLH+BSO | 89 | <ul style="list-style-type: none"> 1 (8.3%) 1 vaginal mucosal tearing required suture ligation | <ul style="list-style-type: none"> 4 (33.3%) 1 vaginal bleeding (cauterization with silver nitrate) 2 persisting vaginal spotting 1 umbilical port-site cellulitis | 0 | Outpatient < 24h | NA | NA | NA | NA |
| Jeftovic 2018 (18) | 32 | HLT+BSO +gender affirmation surgery +/- mastectomy | 76 | <ul style="list-style-type: none"> 1 (3%) 1 pelvic hematoma | NA | 0 | 4.5 | NA | NA | NA | NA |
| Current study | 49 | TLH with BSO | 96 | <ul style="list-style-type: none"> 3 (6.1%) 3 vaginal bleeding (required vaginal suture) | <ul style="list-style-type: none"> 6 (12.24%) 5 vaginal bleeding 1 infection of vaginal cuff | 0 | Outpatient < 24H | 0 (0%) | 2.2 | 2.4% Regular 81% Good 16.7% Excellent | 3-37 (range) |

Abbreviations: OT, operative time; min, minutes; LAVH, laparoscopically assisted vaginal hysterectomy; NA, not available; TLH, total laparoscopic hysterectomy; BSO, Bilateral salpingo-oophorectomy; VAS: Visual Analog Scale. ^aValues are given as mean or number (percentage)

CONFLICTS OF INTEREST

The authors declare that they have no conflicts of interest and nothing to disclose.

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