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Transoral robotic surgery versus conventional transoral surgery for submandibular stones: Systematic review and meta-analysis

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ABSTRACT

Purpose: The recent diffusion of transoral robotic surgery has prompted its application not only in the oropharyngeal and hypopharyngeal-laryngeal fields, which are the anatomical sites of major use of the method, but also in the oral floor for the removal of tumours and other diseases affecting the salivary glands, such as sialothiasis. This study aims to assess the safety and efficacy profiles of transoral robotic surgery compared to traditional transoral procedures for the treatment of submandibular stones.

Methods: PubMed, Embase, and Web of Science were searched for studies reporting on traditional or robotic transoral surgery for submandibular stones. As recommended by the PRISMA guidelines, proportion meta-analysis was performed on a random-effects model. The present review was registered on PROSPERO (CRD42024522199).

Results: A total of 2520 participants from 23 studies were included. The selected patients had a mean age of 44 years (range 5-87), with 48 % of them being female. Transoral robotic surgery had a success rate of 95.7 % (95 % CI 90.9-99.0), higher than traditional transoral approaches (success rate 92.6 %; 95 % CI 89.3-95.4). Transient *stupor* of the lingual nerve was observed more frequently in robotic surgeries (15.8 % vs 8.1 %). However, no reports of permanent injury to the lingual nerve were found.

Conclusion: Transoral robotic surgery is a valid treatment option for submandibular stones. Due to the high costs of the procedure, strict patient selection is mandatory.

1. Introduction

The advancements in robotic surgery achieved significant results in a broad range of medical specialties, lowering patient discomfort and complication rates [1]. Improved 3D-HD imaging of the surgical field, physiological tremor attenuation, the capacity to execute micromovements with a far better degree of precision than human hands, and an ergonomic surgical environment have all been made possible by robotic surgery [2]. Transoral robotic surgery has been used in head and neck surgery for different conditions, including cancer, obstructive sleep apnoea, and submandibular lithiasis [3–5].

Transcervical sialoadenectomies were the preferred treatment option for submandibular stones; however, these procedures carried the risk of damaging the marginal mandibular nerve and leaving unesthetic scars [5,6]. Therefore, several minimally invasive techniques have been developed over time to remove the stone without damaging the

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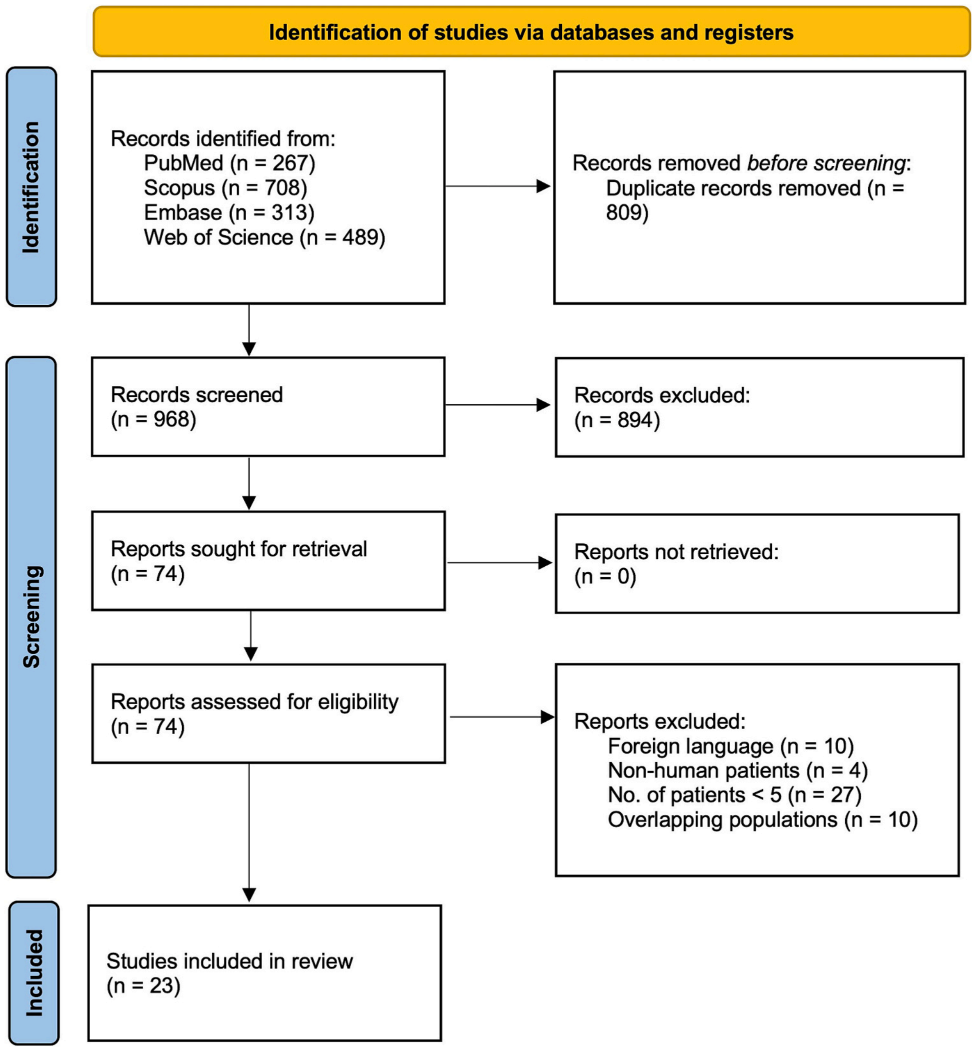

Fig. 1. PRISMA flowchart of the study selection process for the present systematic review and meta-analysis.

glandular parenchyma or the patency of the duct [6]. These advancements have substantially reduced the need for submandibular sialadenectomy [7]. Stone size, location, mobility, and shape have been recognised as important prognostic factors for transoral minimally invasive surgeries of the submandibular gland [8]. Indeed, for stones smaller than 4 mm, interventional sialendoscopy alone is usually sufficient [9]. Intraductal shock-wave lithotripsy is the first line of treatment for larger stones in European countries [6]; however, transoral transductal surgery, eventually combined with sialoendoscopic assistance, is advised in the event of failure or stones unreachable with the sialendoscopic probe [6].

More recently, promising studies on transoral robotic surgery combined with sialendoscopic assistance for treating submandibular lithiasis have been published. [9–11] These reports emphasize the possibility of making smaller incisions and underscore the importance of the greater resolution in the surgical field granted by the robotic system, which aids in the identification and preservation of the neurovascular structures of the oral floor. Transoral robotic surgery has been described as an effective therapeutic option for hilo-parenchymal submandibular stones by Rogalska et al. [5] in their systematic review. However, no meta-analysis has yet been conducted to provide a quantitative synthesis of the individual studies' outcomes. We aim to address this gap and to evaluate the success and complication rates of these two surgical techniques in order to draw more thorough conclusions about their safety and effectiveness in an evidence-based perspective.

2. Material and methods

This study was reported in compliance with the PRISMA 2020 declaration [12] and the Cochrane Handbook for Systematic Reviews of Interventions [13] standards.

2.1. Eligibility criteria

Studies that fulfilled the following inclusion criteria were included in this meta-analysis: (1) observational studies or randomized controlled trials; (2) enrolling at least five patients with submandibular stones; (3) undergoing transoral robotic surgery or traditional transoral surgery; and (4) with clear reports on the procedure success rates.

2.2. Search strategy and data extraction

PubMed, Embase, Scopus, and Web of Science were screened in May 2024 for English-written studies published between 2004 and 2024 using the following search strategy: ("submandibular" OR "salivary" OR "gland" OR "hyloparenchymal") AND ("sialolithiasis" OR "sialolith" OR "megalith" OR "stone") AND ("transoral" OR "transoral surgery" OR "surgery" OR "robot" OR "robotic" OR "robot-assisted" OR "robotic assisted"). The references from all included studies and previous reviews were also searched manually for any additional records. The prospective meta-analysis protocol was registered on PROSPERO

Table 1
Baseline characteristics of the study populations.

Study	Country	No. of patients	Mean age (range)	No. of men	No. of Women	Stone size (mm)	Type of surgery	Sialoendoscopic assistance	Successes	Overall complications	Follow up (months)
Capaccio 2017 [18]	Italy	479	46 (19-81)	244	235	9.0	Conventional	Yes	472	133	12
Coca 2022 [19]	USA	16	53	4	12	9.3	Conventional	/	15	/	/
Costan 2019 [20]	Romania	32	42 (17-67)	17	15	/	Conventional	No	32	2	12
Eun 2010 [21]	South Corea	22	/	/	/	5.2	Conventional	No	22	0	/
Gerni 2017 [22]	France	30	42 (19-87)	15	15	5.6	Conventional	Yes	25	0	/
Holden 2019 [23]	UK	378	/	/	/	8.6	Conventional	Yes	356	89	12
Juul 2014 [24]	Denmark	42	51 (14-85)	19	23	10.0	Conventional	/	39	27	18
Kim 2015 [25]	South Corea	125	40 (5-76)	62	63	7.3	Conventional	/	104	7	58
Lim 2020 [26]	Australia	10	47	6	4	8.0	Conventional	Yes	9	4	8
Park 2012 [27]	South Corea	150	/	72	78	/	Conventional	No	145	30	/
Roh 2008 [28]	South Corea	59	34 (7-72)	32	27	7.0	Conventional	No	54	3	24
Romero 2019 [29]	USA	164	48	75	89	7.5	Conventional	No	147	5	/
Saga-Gutierrez 2019 [30]	Spain	33	49 (18-86)	15	18	10.2	Conventional	Yes	32	7	14
Salehpour 2022 [36]	Iran	63	45	43	25	1.3	Conventional	Yes	45	7	/
Schwartz 2015 [31]	Israel	39	46	26	13	/	Conventional	No	37	6	8
Shashinder 2011 [32]	New Zeland	60	/	32	28	/	Conventional	No	53	/	6
Sánchez-Barrueco 2023 [33]	Spain	29	46 (19-74)	/	/	5.1	Conventional	Yes	25	/	/
Su 2010 [34]	China	18	/	/	/	15.0	Conventional	Yes	17	4	18
Tarazis 2024 [35]	Greece	138	/	/	/	10.4	Conventional	Yes	120	/	43
Zhao 2020 [37]	China	514	38 (9-86)	/	/	7.4	Conventional	Yes	478	11	40
Razavi 2015 [16]	Egypt - USA	22	47 (22-81)	11	11	12.3	Robotic	Yes	22	4	14
Seif-Elnas 2023 [17]	Egypt - USA	60	48	30	30	9.6	Robotic	Yes	57	10	24
Wen 2021 [10]	USA	37	57 (26-80)	22	15	12.4	Robotic	Yes	34	5	34

No. = number, mm = millimeters

(CRD42024522199). Two authors (M.L. and G.B.) independently reviewed the full texts and abstracts. Disagreements were resolved through consensus. To mitigate publication bias, only studies reporting on at least 5 patients with submandibular stones undergoing transoral surgery were included in this review. If there was patient overlap among the studies, only the largest cohort was included. The search strategy was limited to articles published within the last two decades, as this timeframe marks the development and spread of combined approaches for submandibular stones, following the introduction of sialendoscopy.

For each study the following information was acquired by two review authors (ML, GB): name of the first author, country in which the study was performed, year of publication, study design, number of patients included, mean age and sex of the enrolled patients, time of follow up, stone location (ductal, hilo-parenchymal, parenchymal), surgical time of the procedure, number of successful surgeries, complications (transient or permanent lingual nerve injury, infection, bleeding, ranula formation). Extracted data was compared and discrepancies were resolved through consensus.

2.3. Quality assessment

Version 2 of the Cochrane Risk of Bias assessment tool [14] was used to assess the risk of bias in randomized studies. The Risk of Bias in Non-randomized Studies - of Interventions tool [15] (ROBINS-I) was used to evaluate non-randomized studies. The risk of bias evaluation was performed by two independent authors (M.R. and E.F.). Disagreements were resolved by a third author (M.L.) if needed.

2.4. Statistical analysis

The success rate with 95 % confidence intervals following therapy for submandibular stones was the main outcome of our analysis. Proportion meta-analysis was used to address it effectively, considering the lack of comparative studies between robotic and traditional transoral surgery. Proportion meta-analysis is a statistical method usually employed to synthetise evidence, such as proportions or prevalence, from single group studies. Effects of the different treatments for submandibular stones, study designs, and sample characteristics were deemed to be variable. Therefore, a random effects model was chosen, as well as the Freeman–Tukey double-arcsine transformation. Secondary

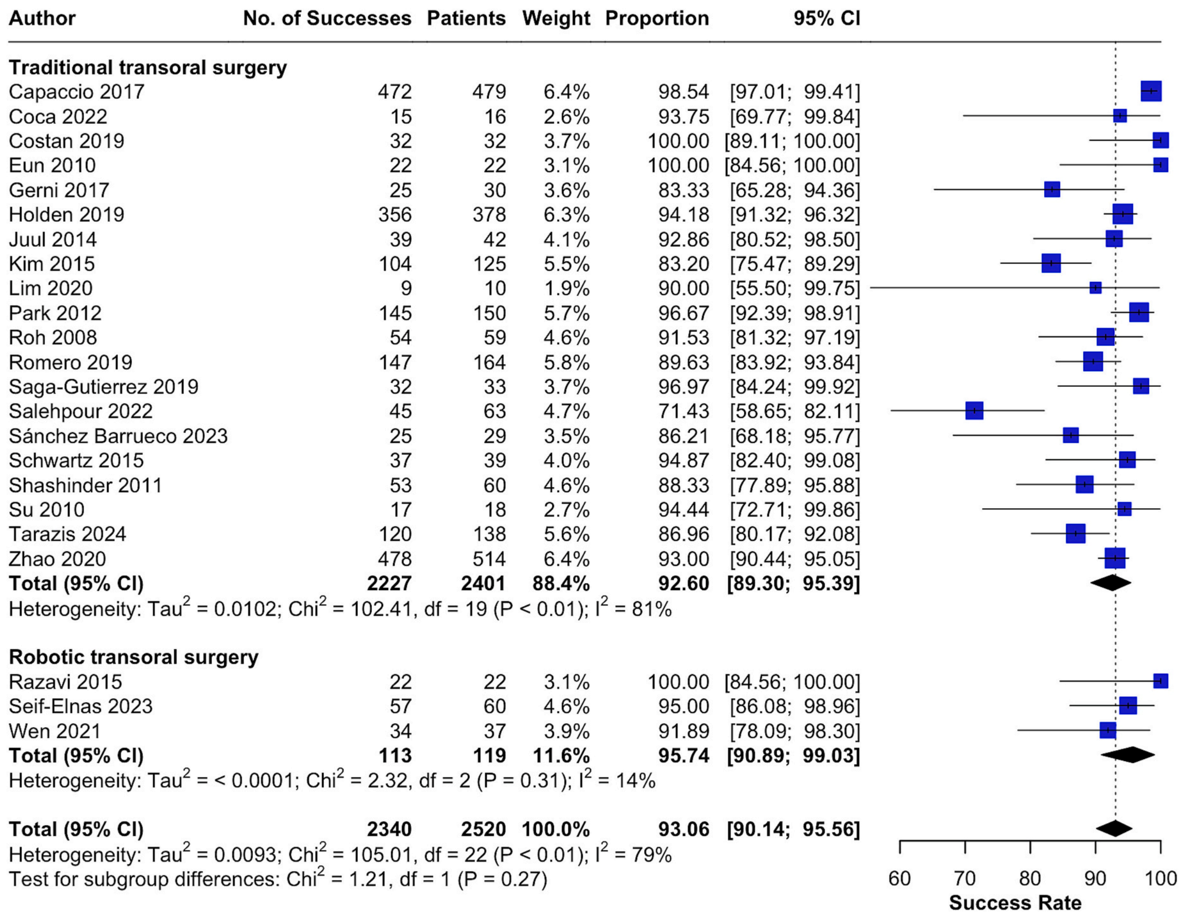

Fig. 2. Forest plot reporting on the overall success rates of treatments for submandibular stones. Robotic procedures showed success rates of 95.7 % (95 % CI 90.9-99.0; $I^2 = 14$ %), conventional transoral sugery 92.6 % (95 % CI 89.3-95.4; $I^2 = 81$ %).

outcomes investigated by this study were overall complication rates, with a focus on transient/permanent risk of injury to the lingual nerve. We assessed heterogeneity with I^2 statistics and Cochrane Q test; *p*-values <0.10 and $I^2 > 40$ % were considered significant for heterogeneity. Publication bias was investigated by funnel-plot analysis of point estimates in relation to study weights. R statistical software (version 4.4.0, 2024-04-24) was used for statistical analysis.

3. Results

A total of 1777 records were retrieved from PubMed, Web of Science, Embase, and Scopus. After duplicate removal, we screened 968 records, from which 74 were reviewed in full-text, and 23 papers were included in our analysis [10,16–37]. Later, we searched the references of the previous systematic review [5] and of the included articles. However, no extra articles that fulfilled the inclusion criteria were found. There were 21 observational studies [10,16–20,22–37] and 2 randomized studies [21,28]. The PRISMA flowchart of the study selection can be found in Fig. 1.

3.1. Baseline characteristics

The included studies comprised 2520 patients with submandibular stones, of which 48 % were females. The mean age of the included patients was 44 years old, the sialoliths` mean diameter was 8.4 mm, and the mean duration of follow-up was 22 months. Further information on the baseline characteristics is shown in Table 1.

3.2. Treatment and pooled analyses

119 patients from 3 studies underwent transoral robotic surgery, while 2401 from 21 studies were treated with conventional transoral surgery. As shown in Fig. 2, the overall success rates of the procedures were 93.1 % (95 % CI 90.1-95.6; $p < 0.01$; $I^2 = 79$ %). Transoral robotic surgery showed success rates of 95.7 % (95 % CI 90.9-99.0; $p = 0.31$; $I^2 = 14$ %), while traditional surgery found a lower success rate of 92.6 % (95 % CI 89.3-95.4; p < 0.01; $I^2 = 81$ %); however, no statistically significant differences between groups were found ($p > 0.05$, test for subgroup differences). Further subgroup analysis focused on those studies that presented results of surgeries on hilo-parenchymal stones (Fig. 3) or surgeries performed using sialoendoscopic-assisted procedures (Fig. 4). Regarding complications (Fig. 5), the aggregated complication rate for transoral robotic surgery was 15.8 % (95 % CI 9.5-23.1; $p = 0.87$; $I^2 = 0$ %), while for traditional surgery it was 13.0 % (95 % CI 6.3-21.6; $p < 0.01$; $I^2 = 97$ %). Further analysis investigated the incidence of transient and permanent injuries after transoral surgery: as reported in Fig. 6, transient damage to the lingual nerve was observed in 15.8 % (CI 9.5-23.1; p = 0.87; $I^2 = 0$ %) in the robotic cohort, while in 8.1 % (95 % CI 3.8-13.6; p < 0.01; $I^2 = 94$ %) in the traditional transoral surgery cohort. Lastly, Fig. 7 shows how the rate of permanent lingual nerve damage was 0.0 % (95 % CI 0.0-1.53; $p = 0.94$; $I^2 = 25$ %) in the robotic group and 0.6 % (95 % CI 0.01-1.70; $p = 0.09$; $I^2 = 41$ %) for patients receiving traditional transoral surgery. No statistically significant differences between groups were found in any subgroup analysis for complications.

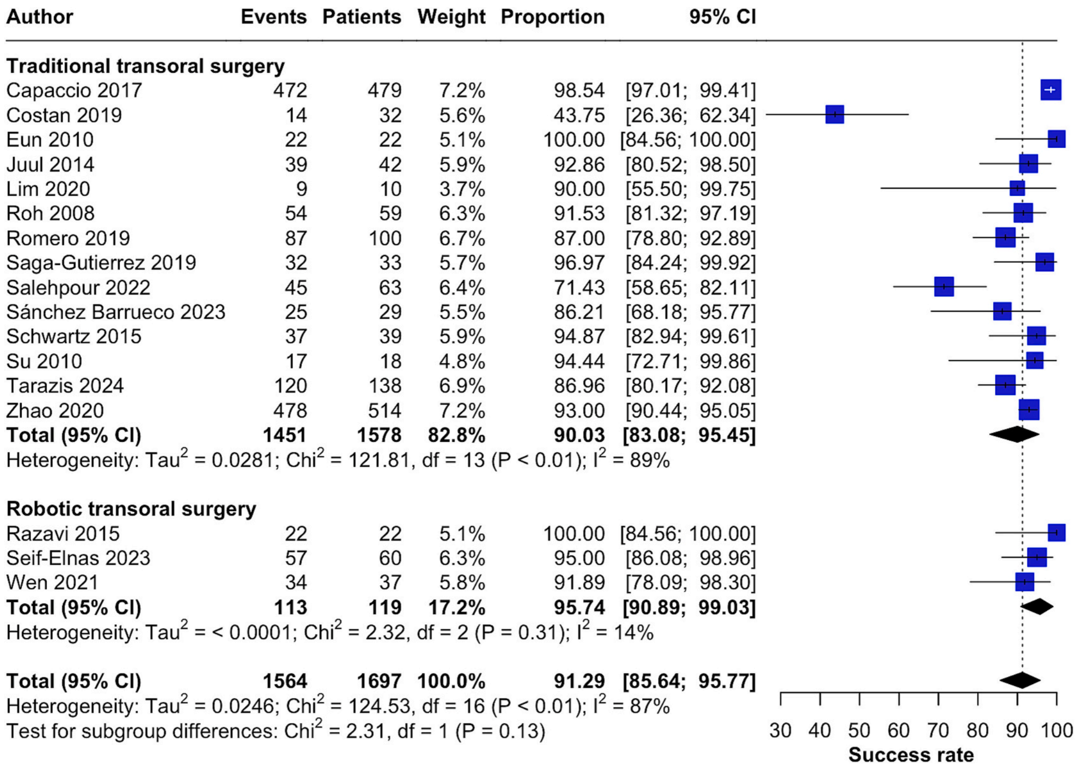

Fig. 3. Forest plot reporting on the success rates of traditional and robotic surgeries on hilo-parenchimal submandibular stones only. Robotic procedures showed success rates of 95.7 % (95 % CI 90.9-99.0; $I^2 = 14$ %), while traditional transoral procedures 90.0 % (95 % CI 83.1-95.5 %; $I^2 = 89$ %).

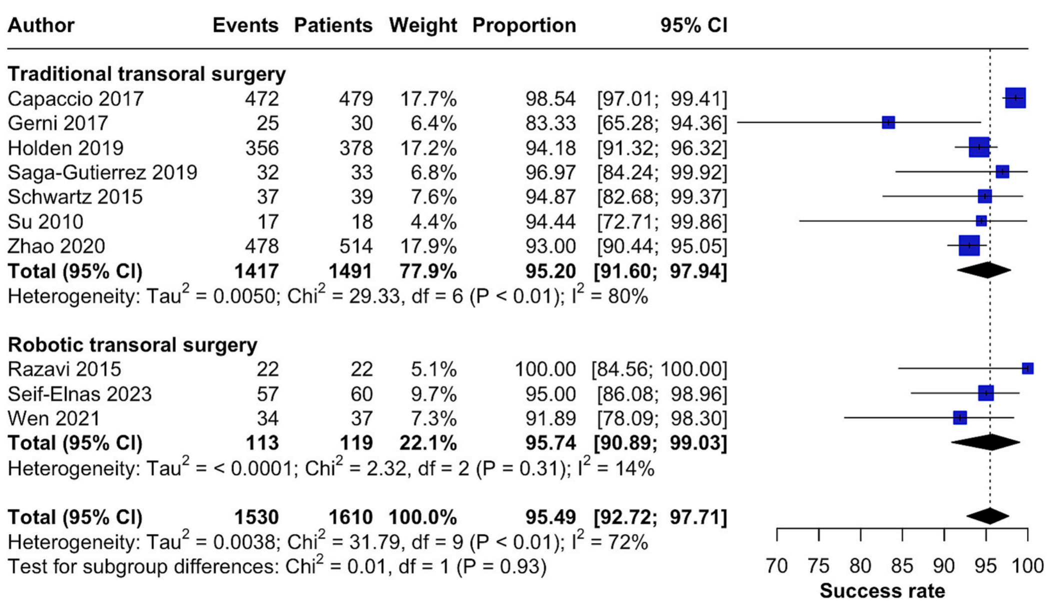

Fig. 4. Forest plot reporting on the success rates of surgeries performed by means of sialoendoscopic-assisted procedures. Both procedures showed similar success rates: 95.7 % (95 % CI 90.9-99.0; $I^2 = 14$ %) for transoral robotic surgery, 95.2 % (95 % CI 91.6-97.9; $I^2 = 80$ %).

3.3. Quality assessment

The 21 observational studies [10,16–20,22–37] included in our analysis were evaluated through the ROBINS-I tool: among these 20 were judged at “moderate” [10,16–20,22,24–27,29–37] and 1 at “serious” risk of bias [23] as reported in Supplementary file 1. The two randomized studies [21,28] were evaluated through RoB-2 and deemed to have “some concerns” at risk of bias assessment as reported in Supplementary file 1. In the funnel plot provided in Supplementary file 1, the distribution of studies does not appear symmetric, suggesting publication bias across the included studies.

4. Discussion

This meta-analysis comprising 2520 patients from 23 studies has assessed the efficacy and safety profile of robotic and conventional transoral surgery for the treatment of submandibular stones. To the best of our knowledge, this is the first meta-analysis to compare transoral

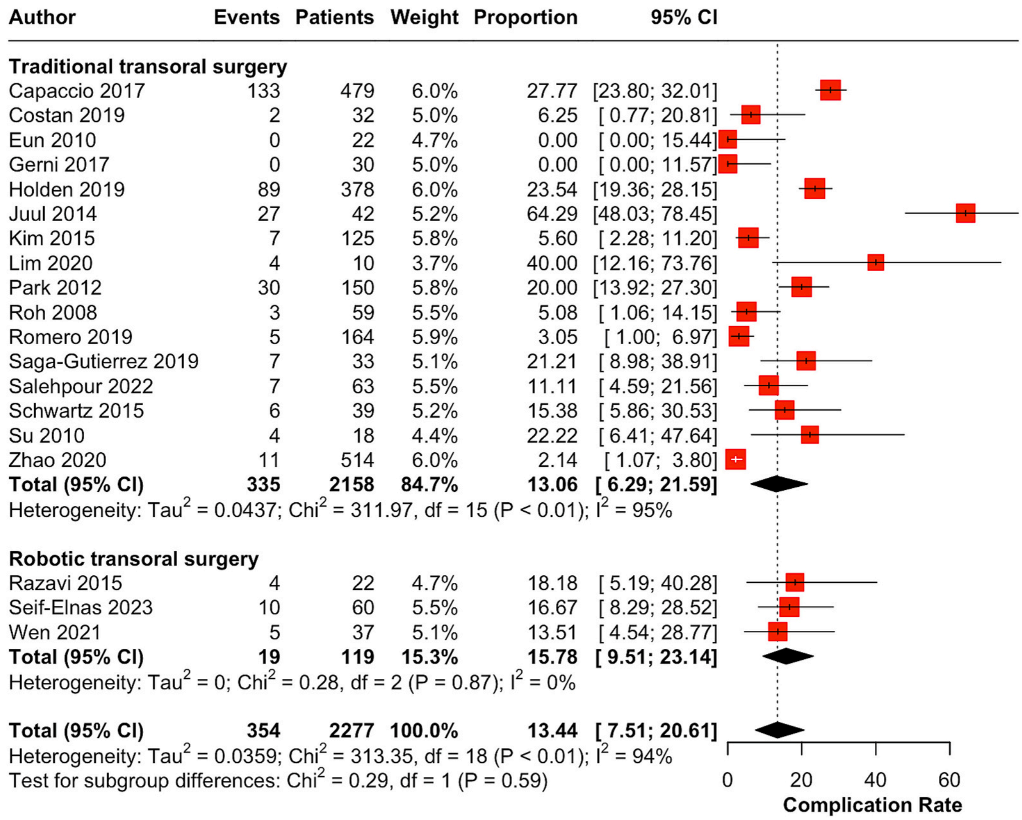

Fig. 5. Forest plot reporting on the overall complication rates of treatments for submandibular stones. The complication rate for robotic transoral surgery was 15.8 % (95 % CI 9.5-23; I^2 = 0 %), while for traditional transoral surgery 13.1 % (95 % CI 6.3-21-6; I^2 = 95 %).

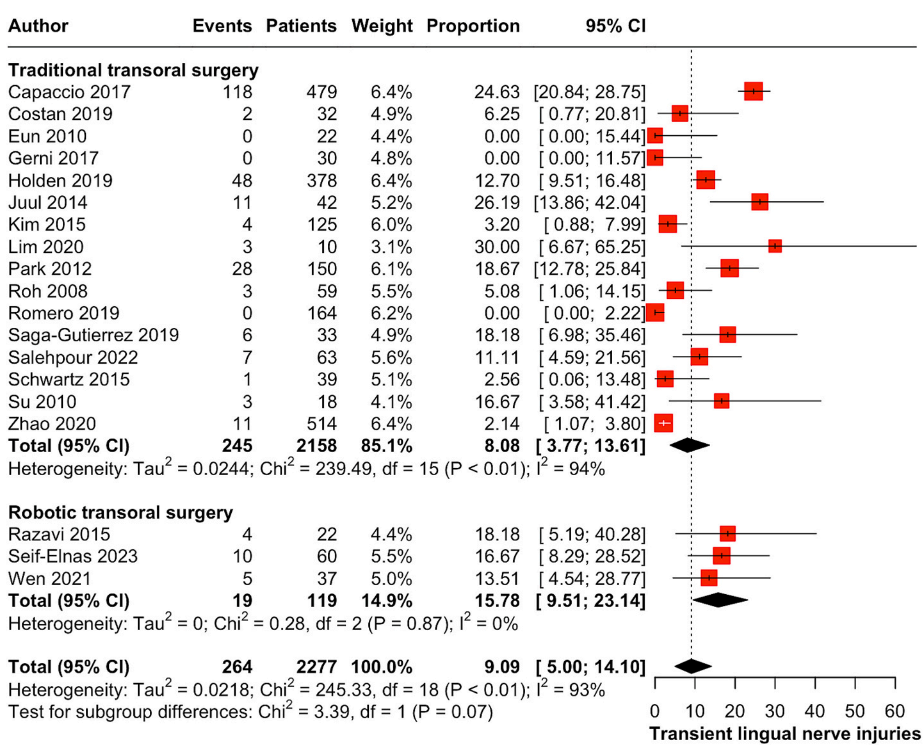

Fig. 6. Forest plot reporting on the prevalence of transient lingual nerve injuries after transoral robotic surgery or traditional transoral surgery. The occurrence of this complication was found to be 15.8 % (95 % CI 9.51-23.1; I^2 = 0 %) in robotic transoral surgery, and 8.1 % (95 % CI 3.8-13.6; I^2 = 94 %) in traditional transoral surgery.

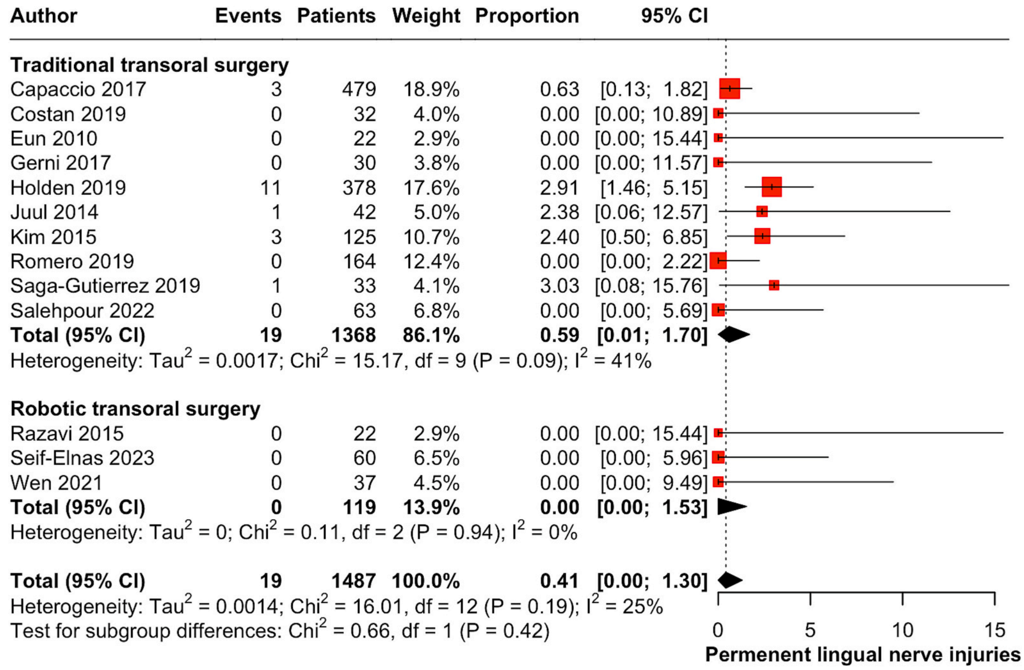

Fig. 7. Forest plot reporting on the prevalence of permanent lingual nerve injuries after transoral robotic surgery or traditional transoral surgery. No permanent damage to the lingual nerve was described following robotic transoral surgery.

robotic surgery with conventional transoral surgery. The success rates of robotic procedures were higher and more consistent compared to traditional transoral surgeries (Fig. 2). The overall complication rates of the two procedures were similar: 15.8 % for robotic transoral surgery and 13.0 % for traditional surgery (Fig. 5). Regarding the risk of lingual nerve damage, even if the prevalence of transient nerval stupor was higher in robotic procedures, no permanent lingual nerve injury had yet been described in literature (Figs. 6 and 7).

The overall success rates of transoral surgery for submandibular stones were notably high (93.1 % 95 % CI 90.1-95.6; $I^2 = 79$ %). The sporadic failures of traditional approaches have been associated with inadequate visualization of anatomical landmarks in the oral floor, especially in the case of hilo-parenchymal stones, due to the deep and limited surgical area [38]. Conversely, unfavourable factors such as chronic inflammation [11] or limited mouth opening and a narrow mandibular arch [6,10], which can limit the robotic arms' motility, may be linked to cases of failure in transoral robotic surgery.

Regarding complication rates of the procedures, those of robotic surgery were higher than the ones granted by traditional transoral surgery. Our results show a more frequent, although not statistically significant incidence of transient lingual nerve injury with robotic surgery. This could be explained by the lack of tactile feedback during robotic surgery for the first operator [17,39,40], which leads to an inability to assess the amount of traction applied to the tissues, despite the enhanced maneuverability. Ultimately resulting in unintentionally excessive traction that causes transient lingual nerve deficits. To the best of our knowledge, however, there have not been any documented reports of permanent lingual nerve damage following robotic transoral surgery in the literature. Indeed, the 3D-HI magnification provided by the robotic console aids in the preservation of the fragile neurovascular structures of the oral floor [10,17], providing excellent outcomes in the long term. Lastly, transoral robotic surgery is characterized by a long learning curve and complication rates typically decrease as the surgeon's experience advances [10].

Most of the procedures in both cohorts of patients were performed with sialendoscopic assistance. To address potential variability deriving from the use of this device across the studies included in the present meta-analysis we have performed a further subgroup analysis, as shown in Fig. 4. However, no statistically significant differences between groups were found. Sialendoscopy is not the mainstay of transductal surgery, but it can indeed be used to evaluate to the glandular hilum at the end of the procedure to enhance the therapeutic effectiveness, as it aids the identification and removal of possible residual microliths [41]. Sialendoscopy can also aid in locating the stone at the beginning of the surgical procedure in case of pure parenchymal stones of difficult palpability, thanks to the bright guidance of the probe that is able to direct the surgeon in the operatory field [18,30].

Interestingly, only a few of the include studies provided information regarding stone palpability [16–18,20,22,25,26,28,37]. This has prevented us from conducting further subgroup analysis and is likely partially responsible of the high I^2 observed in our analysis. Palpation is important in transoral approaches to submandibular stones, to the point that McGurk et al. stated that unpalpability should be considered a contraindication for intraoral stone removal [42]. Later reports have shown that even in cases of unpalpable stones a conservative transoral approach can still be feasible [21]. In robotic transoral surgery Capaccio et al. [41] have suggested to always provide an accurate pre-operative counselling (with double surgical consent administration) to patients, in order to make them aware of the possibility of conversion to submandibular sialadenectomy, in case of impossibility to intra-operatively detect a non-palpable pure parenchymal stone.

Lastly, the mean operative time exceeded 60 min in robotic transoral approaches to submandibular stones [16,17], generally longer than the times reported in studies on traditional transoral surgery [21,27,29,30]. This might reflect the additional time required in the docking phase to correctly position the robot and, possibly, the learning curve associated with the increasing experience of the surgeon.

Our study has limitations. First, there is a small sample size of patients who underwent transoral robotic surgery, due to it being a relatively new surgical treatment in which further contributions are still needed. Another limitation concerns the high heterogeneity observed in our results, that is the consequence of a high variability of the included studies in terms of design, population, stone's characteristics, surgical technique and outcomes. To address this, we conducted additional subgroup analysis based on stone location and sialendoscopic support during surgery (Figs. 3 and 4) and performed a quality assessment

(Supplementary file 1). Lastly, different authors have defined treatment success in different ways. For example, some have focused on patients with no symptoms, while others have focused on complete stone removal.

5. Conclusion

This systematic review and meta-analysis found that transoral robotic surgery can be regarded as a safe, effective method for treating submandibular gland stones, with comparable success and complication rates to traditional treatments. However, due to its high cost, this kind of treatment should only be used for patients with certain anatomical features that would make typical transoral surgery less advantageous, such as deeply positioned hiloparenchymal stones.

CRediT authorship contribution statement

Matteo Lazzeroni: Writing – original draft, Project administration, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Giulia Bucchichini:** Writing – review & editing, Investigation, Formal analysis, Data curation. **Muhammad Suleiman:** Writing – review & editing, Methodology, Investigation, Data curation. **Emma Finnegan:** Writing – review & editing, Validation, Formal analysis, Data curation. **Luke Mattey:** Writing – review & editing, Visualization, Data curation. **Davide Tosini:** Writing – review & editing, Supervision, Methodology, Data curation. **Michele Proh:** Writing – review & editing, Validation, Supervision, Methodology, Investigation. **Lorenzo Pignataro:** Writing – review & editing, Validation, Supervision, Methodology. **Antonino Maniaci:** Writing – review & editing, Validation, Supervision, Methodology. **Mario Lentini:** Writing – review & editing, Validation, Supervision. **Sara Torretta:** Writing – review & editing, Visualization, Validation, Supervision. **Pasquale Capaccio:** Writing – review & editing, Visualization, Validation, Supervision, Project administration, Methodology, Investigation. **Michelle Azevedo:** Writing – review & editing, Visualization, Validation, Supervision, Project administration.

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Declaration of competing interest

The authors have no financial or non-financial interests directly or indirectly related to the work submitted for publication to disclose.

Appendix A. Supplementary data

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