

doi: 10.3978/j.issn.2095-6959.2019.09.023

View this article at: <http://dx.doi.org/10.3978/j.issn.2095-6959.2019.09.023>

Meta 分析超声引导下经皮微波消融术与甲状腺切除术 治疗甲状腺乳头状微小癌的效果

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[摘要] 目的: 系统评估超声引导下经皮微波消融术与甲状腺切除术治疗甲状腺乳头状微小癌(papillary thyroid microcarcinomas, PTMCs)的疗效。方法: 从PubMed, Google Scholar, Cochrane Library, 万方, CNKI等各大数据库中检索2015至2018年的超声引导下经皮微波消融术或甲状腺切除术治疗PTMCs的临床研究, 对符合标准的4篇文献进行Meta分析。结果: 经过数据提取及统计学分析, 与手术组相比, PMWA组住院时间短、术中出血量少、手术时间短, 差别均有统计学意义。术后并发症对比结果显示, 消融组术后短暂性喉返神经麻痹、短暂性手足麻木发生率低于手术组, 差别有统计学意义。两组永久性并发症发生率无显著差异。术前术后甲状腺相关激素Meta分析结果显示PMWA术对于甲状腺功能影响较小。研究中包括的所有患者均未发生复发、淋巴结转移。结论: 对于诊断明确, 分层清晰的低风险PTCs患者, 可选择PMWA术。对于术前诊断不明确、无法判断淋巴结转移情况的中、高危患者, 手术治疗是最佳选择。

[关键词] 微波消融术; 甲状腺切除术; 甲状腺乳头状癌; 并发症

Meta-analysis of the curative effect of ultrasound-guided percutaneous microwave ablation and thyroidectomy on the treatment of patients with papillary thyroid microcarcinoma

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Abstract **Objective:** To systematically evaluate the efficacy of ultrasound-guided percutaneous microwave ablation and thyroidectomy in the treatment of papillary thyroid microcarcinoma. **Methods:** The PubMed, Google scholar, Cochrane Library, Wanfang, CNKI databases were searched, and the clinical studies on ultrasound-guided percutaneous microwave ablation or thyroidectomy for the treatment of papillary thyroid microcarcinoma were selected. The search time was from 2015 to 2018, and Meta-analysis was performed on 4 articles that met the

收稿日期 (Date of reception): 2019-02-18

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inclusion criteria. **Results:** After data extraction and statistical analysis, compared with the operation group, the microwave ablation group had shorter hospitalization time, less intra-operative blood loss and shorter operation time, and the differences were statistically significant. The comparison of postoperative complications showed that the incidence of transient recurrent laryngeal nerve palsy and transient hand and foot numbness in the ablation group was lower than that in the operation group, and the difference was statistically significant. There was no significant difference in the incidence of permanent complications between the two groups. Preoperative and postoperative thyroid hormone Meta-analysis results showed that microwave ablation had little effect on thyroid function. None of the patients included in the studies had recurrence or lymph node metastasis. **Conclusion:** Microwave ablation is an option for low-risk PTCs patients with definite diagnosis and clear stratification. Surgical treatment is the best choice for middle and high-risk patients with unclear preoperative diagnosis and inability to judge lymph node metastasis.

Keywords microwave ablation; thyroidectomy; papillary thyroid carcinoma; complications

甲状腺乳头状癌(papillary thyroid carcinoma, PTC)是甲状腺癌最常见的类型^[1]。甲状腺乳头状微小癌(papillary thyroid microcarcinomas, PTMCs)是指直径 ≤ 1 cm的PTC。随着超声及细针穿刺技术的发展, PTMCs在PTC中的比例逐年增高, 但其病死率并未上升^[2]。目前, 对PTMCs的治疗存在较大争议。最新的美国甲状腺协会(American Thyroid Association, ATA)指南建议对低风险PTMC积极监测^[3], 但很多学者主张手术治疗PTMC^[4-5]。对于高风险或随访监测依从性差的PTMC患者, 甲状腺切除术是首选手术方式^[6]。随着医学技术的进步, 超声引导下经皮微波消融术(ultrasound-guided percutaneous microwave ablation, PMWA)成为一种治疗新手段, 在治疗肾癌、肝癌及甲状腺良性肿物方面取得了良好的疗效^[7-9], 并且逐渐被应用于PTMC的治疗^[10-11]。早期有热消融术与手术治疗良性甲状腺结节和复发性甲状腺癌的对比较研究^[12-14]。然而, PMWA与手术治疗PTMC的疗效比较尚不清楚。故本研究对PMWA与手术治疗PTMC的疗效差异进行荟萃分析, 客观评价这两种治疗方案的优劣, 以期为临床决策提供参考。

1 资料与方法

此Meta分析遵循系统评审和Meta分析(PRISMA)指南的首选报告项目。

1.1 检索策略

从PubMed, Cochrane Library, Google Scholar, CNKI及万方等各大数据库中检索2015至2018年的相关临床试验文献, 英文检索词为microcarcinoma,

microcarcinoma, small papillary carcinoma, micropapillary carcinoma, incidental carcinoma, thyroid incidentaloma, thyroid cancer, thermal ablation, microwave, microwave ablation, percutaneous microwave ablation, ultrasound-guided percutaneous microwave ablation, thyroidectomy等。中文检索词为PTMCs、甲状腺癌、甲状腺乳头状癌、微波消融、甲状腺切除术等。同时, 对检索到的论文中的参考资料进行了检查, 以进行更多的研究。

纳入标准: 随机对照试验、对照临床试验、或观察性试验; 研究对象为PTMC患者、术前穿刺或术后病理证实诊断; 研究数据包括PMWA与手术治疗PTMC手术时间、出血量、并发症等; 首次接受治疗; 样本量、年龄、语种不限。

排除标准: 复发性PTMC或伴有侧颈部淋巴结转移; 重要数据不全; 无法获取全文; 评论、报告重复的出版物。

1.2 质量评估和数据提取

两位评审员将对所有研究题目和摘要进行独立评估; 然后检索全文, 并根据收录情况评估文章内容的相关性。当出现任何分歧时, 应咨询第三审稿人。主要记录研究题目、第一作者、发表时间、手术相关指标。

1.3 纳入研究的偏倚风险评价

使用Furlan等^[15]推荐的12个项目的标准评估了纳入研究的偏倚风险, 当回答是“是”时, 给每个项目分配一个分数, 而回答是“否”和“不清楚”时则没有分数。研究质量高 >7 分, 中等 $5\sim 7$ 分, 低 <5 分。

1.4 统计学处理

采用RevMan5.3软件进行Meta分析。计数资料采用相对危险度(RR)和优势比(OR)为效应指标,各效应量均给出其点估计值和95%CI。纳入研究结果间的异质性采用 χ^2 检验进行分析(检验水准为 $\alpha=0.1$),同时结合 I^2 定量判断异质性的。若各研究结果间无统计学异质性,则采用固定效应模型进行Meta分析;若各研究结果间存在统计学异质性,则进一步分析异质性来源,在排除明显临床异质性的影响后,采用随机效应模型进行Meta分析。

2 结果

2.1 文献检索结果

通过检索词检索到相关文献1 375篇,经过筛选,最终4篇纳入此Meta分析^[16-19]。其中2篇英文文献,2篇中文文献,均来自中国。筛选流程及结果见图1。文献基本特征及质量评价结果见表1,并绘制风险偏倚图见图2。

2.2 Meta 分析结果

2.2.1 手术时间、住院时间、术中出血量、肿瘤直径
4项研究均记录了手术时间、出血量及住院时间等基本信息。住院时间随机效应模型Meta分析

结果显示PMWA组住院时间短于手术组,差别有统计学意义($MD=-2.79$, 95%CI: $-3.03\sim-2.55$, $P<0.05$)。术中出血量Meta分析结果提示PMWA组出血量少于手术组,差别有统计学意义($MD=-20.68$, 95%CI $-21.41\sim-11.94$, $P<0.05$)。手术时间Meta分析结果显示PMWA组手术时间短于手术组,差别有统计学意义($MD=-38.31$, 95%CI: $-68.85\sim-7.77$, $P<0.05$)。两组肿瘤直径差别无统计学意义($MD=0.03$, 95%CI: $-0.24\sim0.30$, $P>0.05$, 图3)。

2.2.2 术后并发症

4项研究所记录的术后并发症不尽相同,主要包括术后短暂性喉返神经麻痹、短暂性手足麻木、永久性喉返神经麻痹、永久性甲状旁腺功能减退。术后短暂性喉返神经麻痹的Meta分析结果显示组术后短暂性喉返神经麻痹发生率低于手术组,差别有统计学意义($OR=0.35$, 95%CI: $0.13\sim0.95$, $P<0.05$)。术后短暂性手足麻木的Meta分析结果显示PMWA组术后短暂性手足麻木发生率低于手术组,差别有统计学意义($OR=0.09$, 95%CI: $0.01\sim0.72$, $P<0.05$)。永久性喉返神经麻痹的Meta分析结果提示两组发生率差异无统计学意义($OR=0.44$, 95%CI: $0.06\sim3.06$, $P>0.05$)。永久性甲状旁腺功能减退, Li等^[16]记录的数据显示PMWA组0例,手术组9例,其余3项研究所有患者均无永久性甲状旁腺功能减退发生(图4)。

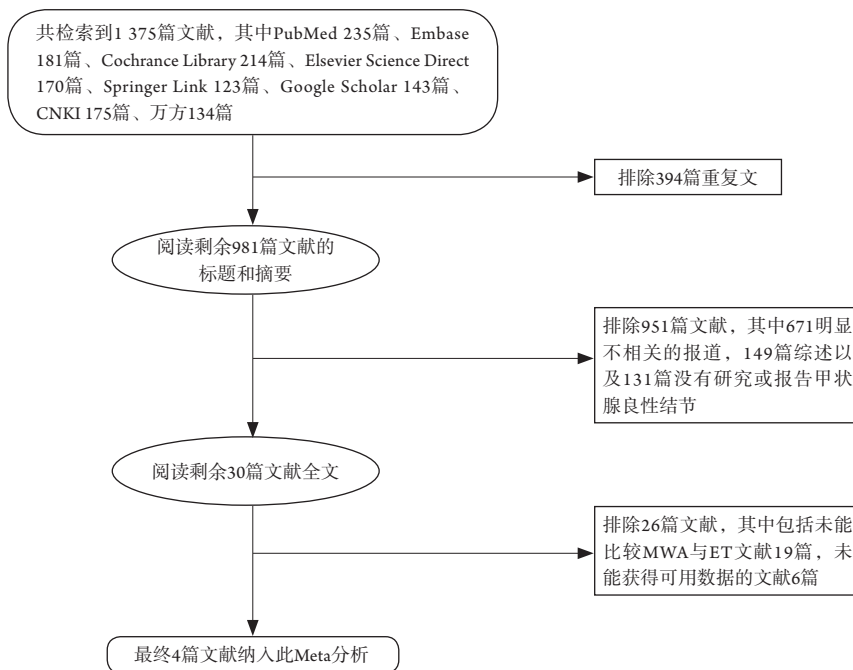


图1 文献筛选流程及结果

Figure 1 Literature screening process and results

2.2.3 微波消融相关数据分析

4项研究中, 微波消融发射频率均为2 450 HMz, 设定功率: Xu等^[19]为50 W, 其余3项研究^[16-18]为30 W。消融时间不等(表2)。图5分别记录了微波消融组

术后肿瘤体积变化(A)以及肿瘤体积减少率(B), 可观察到4项研究其肿瘤体积变化规律基本一致, 在术后1个月时肿瘤体积明显增大, 随后逐渐缩小, 术后24个月基本恢复正常(图5)。

表1 纳入文献的基本特征

Table 1 basic features of the included literatures

纳入文献	发表年份	国家	总病例数	年龄/岁		性别(男/女)/例		随访时间/月	风险偏倚得分
				PMWA术	甲状腺切除术	PMWA术	甲状腺切除术		
Li等 ^[16]	2018	中国	92	43.63 ± 9.27	49.56 ± 9.0	14/32	13/33	30~42	6
马芳花等 ^[17]	2017	中国	75	46.1 ± 8.2	49.97 ± 10.3	5/10	5/8	6	9
陈杭军等 ^[18]	2018	中国	89	44.88 ± 11.04	45.78 ± 13.74	9/40	5/35	24	7
Xu等 ^[19]	2018	中国	87	45.8 ± 10.2	46.2 ± 11.5	12/29	16/30	24~32	8

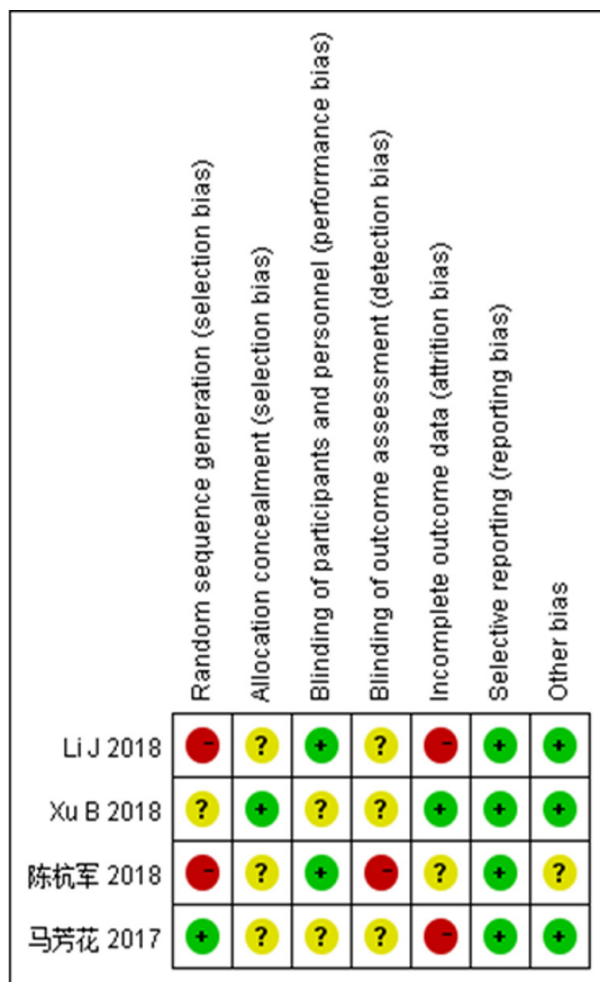
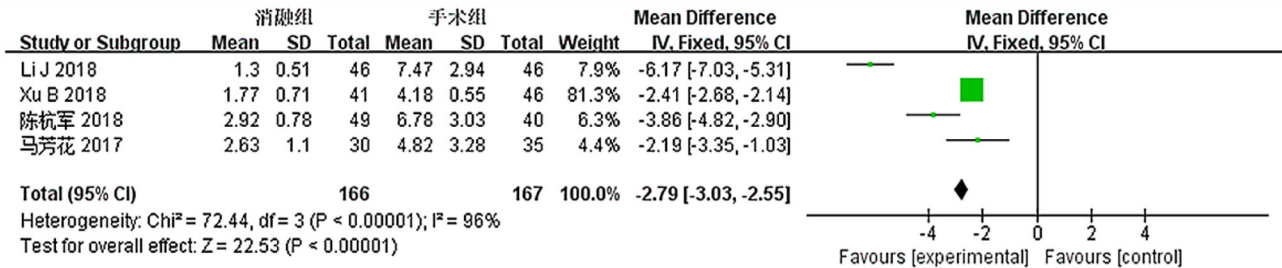


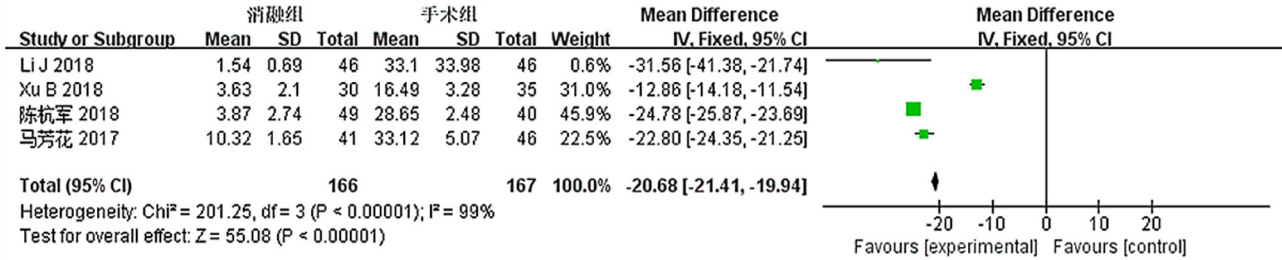
图2 风险偏倚图

Figure 2 Risk bias diagram

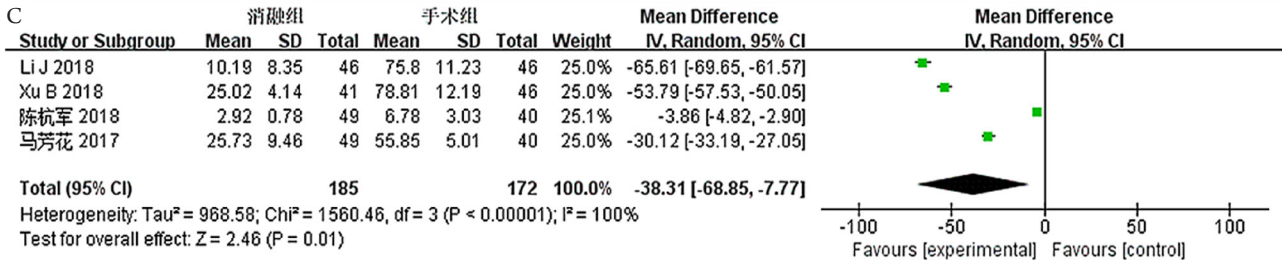
A



B



C



D

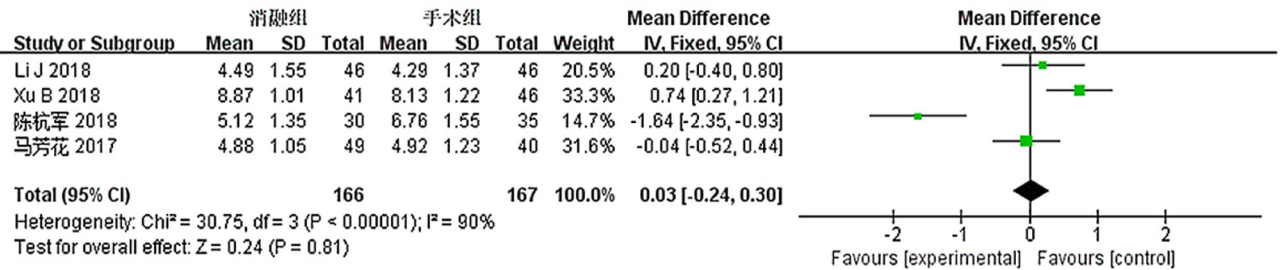


图3 手术时间(A)、术中出血量(B)、平均住院时间(C)、肿瘤直径(D)的森林图; 图A-D中的正方形分别代表手术时间、术中出血量、平均住院时间、肿瘤直径的加权平均差值; 正方形的大小与队列的大小成正比(CI=95%)

Figure 3 Forest diagram of operation time (A), intraoperative blood loss (B), mean hospitalization time (C), tumor diameter (D); The squares in figure (A-D) respectively represent the weighted mean difference of operation time, intraoperative blood loss, average hospitalization time and tumor diameter. The size of the square is proportional to the size of the queue (CI=95%)

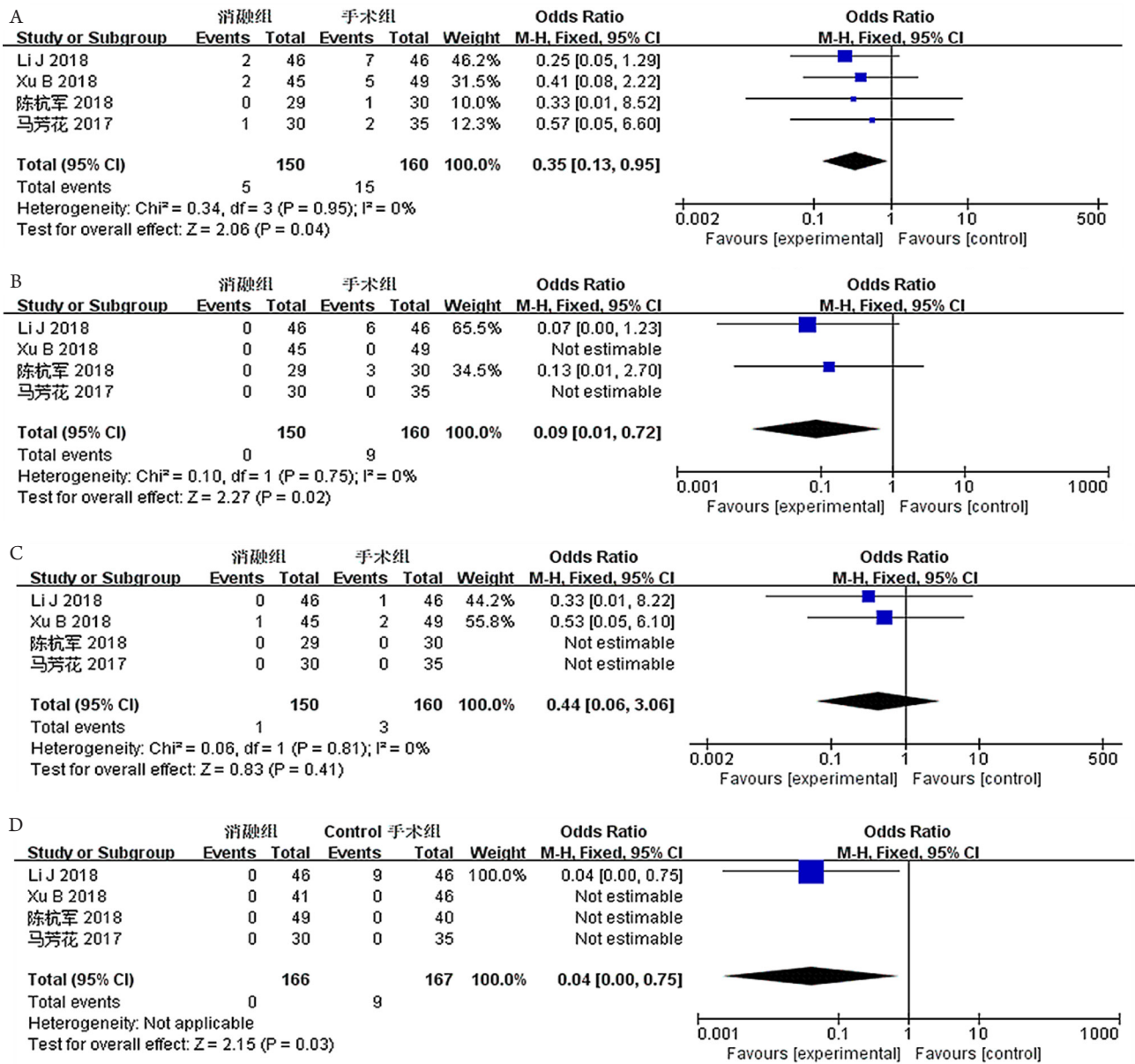


图4术后暂时性喉返神经麻痹(A)、术后暂时性手足麻木(B)、术后永久性喉返神经麻痹(C)、术后永久性甲状旁腺功能减退(D)的森林图；(A~D)中正方形分别代表术后暂时性喉返神经麻痹、术后暂时性手足麻木、术后永久性喉返神经麻痹、术后永久性甲状旁腺功能减退OR值的影响大小；正方形的大小与队列的大小成正比(CI=95%)

Figure 4 Forest map of postoperative temporary recurrent laryngeal nerve paralysis (A), postoperative temporary hand and foot numbness (B), postoperative permanent recurrent laryngeal nerve paralysis (C), postoperative permanent hypoparathyroidism (D). The squares in (A~D) respectively represent the influence of postoperative temporary recurrent laryngeal nerve paralysis, postoperative temporary hand and foot numbness, postoperative permanent recurrent laryngeal nerve paralysis, postoperative permanent parathyroid hypofunction OR value. The size of the square is proportional to the size of the queue (CI=95%)

表2 微波消融相关数据分析

Table 2 Analysis of data related to microwave ablation

纳入文献	发射频率/MHz	消融功率/W	消融时间/min
Li等 ^[16]	2 450	30	20~120
Xu等 ^[19]	2 450	50	60~300
陈杭军等 ^[18]	2 450	30	180~300
马芳花等 ^[17]	2 450	30	40~150

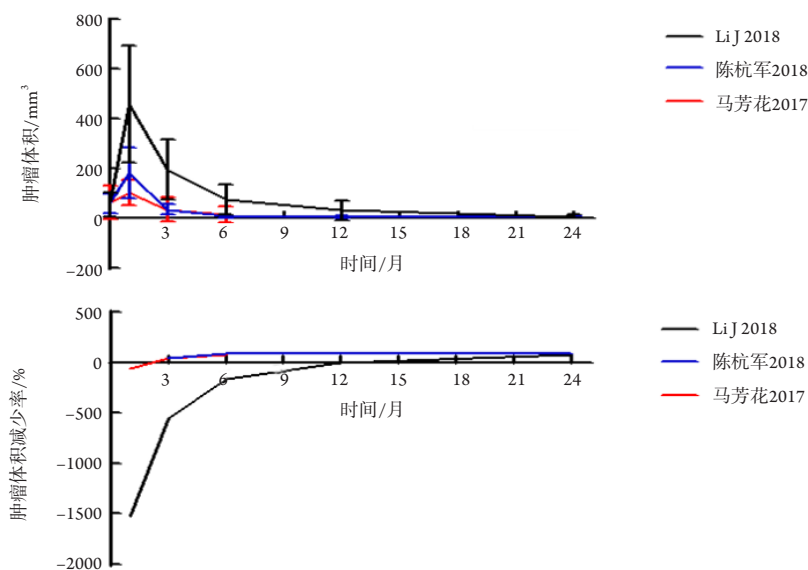


图5 微波消融组术后肿瘤体积变化(A)以及肿瘤体积减少率(B)

Figure 5 Postoperative tumor volume change (A) and tumor volume reduction rate (B) in the microblog ablation group

2.2.4 手术前后甲状腺相关激素的比较

4项研究中有3项^[17-19]详细记录了术前和术后FT3, FT4, TSH变化。PMWA组FT3术前术后Meta分析结果提示术前和术后差异无统计学意义(MD=0.07, 95%CI: -0.06~0.21, $P>0.05$); FT4术前术后Meta分析结果提示手术前后差异无统计学意义(MD=-0.47, 95%CI: -1.12~0.17, $P>0.05$); TSH术前较高, 与术后比较, 差别有统计学意义(MD=-0.71, 95%CI: 0.29~1.14, $P<0.05$)。手术组FT3术后较高, 与术前比较, 差

别有统计学意义(MD=0.86, 95%CI: 0.69~1.03, $P<0.05$); FT4术前高, 与术后比较, 差别有统计学意义(MD=2.13, 95%CI: 1.61~2.66, $P<0.05$); TSH术后较高, 与术前比较, 差别有统计学意义(MD=-16.04, 95%CI: -16.85~-15.23, $P<0.05$, 图6)。

2.2.5 淋巴结转移及局部复发

Li等^[16]、马芳花等^[17]、陈杭军等^[18]3项研究均无患者在随访期间出现局部复发及淋巴结转移, Xu等^[19]未提及复发及淋巴结转移相关数据。

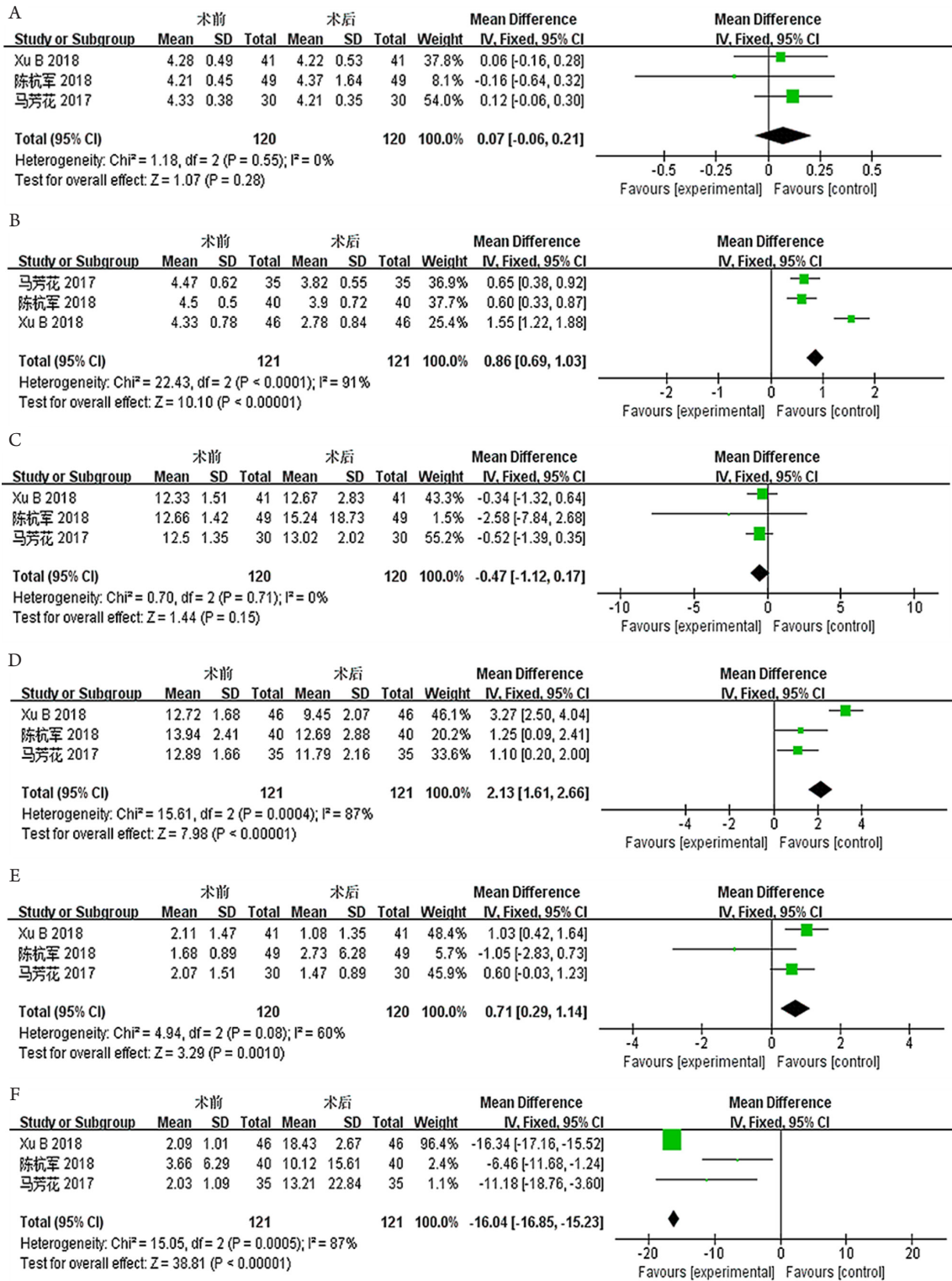


图6 PMWA组FT3 (A)、手术组FT3 (B)、PMWA组FT4 (C)、手术组FT4(D)、PMWA组TSH(E)、手术组TSH(F)术前术后的森林图；图A~F中的正方形分别代表PMWA组FT3，手术组FT3，PMWA组FT4，手术组FT4，PMWA组TSH(E)，手术组TSH(F)术前术后数值的加权平均差值；正方形的大小与队列的大小成正比(CI=95%)

Figure 6 Preoperative and postoperative forest plots of FT3 (A), FT3 (B), FT4 (C), FT4 (D), TSH (E) and TSH (F) in PMWA group, respectively. The squares in Figure A–F respectively represent the weighted average difference of preoperative and postoperative values of FT3, FT3, PMWA, FT4, FT4, TSH (E) and TSH (F) in the PMWA group. The size of the square is proportional to the size of the queue (CI=95%)

3 讨论

随着超声敏感性提高及细针穿刺术的发展, PTMCs发病率越来越高^[20], 但其属于惰性肿瘤, 病死率很低, 国内外对PTMCs的治疗方案讨论成为焦点。一些学者认为PTMCs存在过度治疗, 日本学者提出对低风险PTMCs可在不手术的情况下严密监测^[21-22], 最新的ATA指南进行了相关内容的修改^[3]。目前, 国内对于PTMCs的治疗依然是手术切除为主, 但手术治疗的经济、精神负担不容忽视^[4]。目前, 超声引导的热消融技术发展迅速, 为甲状腺微小癌患者提供了另一种选择^[23]。微波射频消融术在治疗甲状腺良性病变中的价值已经得到认可^[24], 但其在治疗PTMCs中的价值目前仍处于探索阶段。PMWA术与手术治疗PTMCs疗效优劣缺乏客观数据对比, 且现有研究病例数较少, 局限性较多。故本研究通过对PMWA术与手术治疗PTMCs的疗效对比研究进行了系统回顾, 并进行了Meta分析。

本研究共纳入4篇文献, 均来自中国。与手术组相比, PMWA组住院时间短、术中出血量少、手术时间短, 差别均有统计学意义, 说明微波消融组患者手术创伤小, 恢复快。在术后并发症方面, PMWA组术后短暂性喉返神经麻痹、短暂性手足麻木发生率低于手术组, 说明消融组在短暂性并发症方面明显优于手术组, 但长期并发症两组并无差异。手术前后激素水平变化情况反映PMWA组FT3, FT4术前术后变化轻微, TSH术前较高。手术组FT3术后高, FT4术后低, TSH术前较术后低, 证明PMWA术激素水平变化轻微, 对于甲状腺功能影响小, 其TSH术后升高, 可能与术后应激反应引起一过性增高有关。4项研究均提及患者在随访期间均无局部复发及淋巴结转移, 但没有详细数据支撑, 且随访时间差别较大, 故不能得出客观评价。

尽管本研究提示微波消融技术相对于手术治疗创伤小, 出血少, 手术时间短, 术后短期并发症发生率低, 具有较高的临床应用价值。然而对于PTMCs的治疗, 并不能一味追求微创化^[25]。虽然PTMCs危险度低, 但也会出现淋巴结转移, 增加死亡风险^[26]。另外, 如何在准确判断术前淋巴结转移情况, 目前的影像学、病理技术不能满足要求^[27]。术后复发及淋巴结转移风险在本研究中并未得出可靠结论, 因此两种治疗方案在术后复发及淋巴结转移方面是否存在差异, 有待进一步大数据、长期随访的多中心研究进一步明确。

综上所述, 对于诊断明确, 分层清晰的低风险PTC患者, 可选择微波消融术。对于术前诊断不明

确、无法判断淋巴结转移情况的中、高危患者, 手术治疗是最佳选择。

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本文引用: 杨子瑶, 段克南, 秦龙, 熊建霞, 张海涛, 刘静. Meta分析超声引导下经皮微波消融术与甲状腺切除术治疗甲状腺乳头状微小癌的效果[J]. *临床与病理杂志*, 2019, 39(9): 1994-2003. doi: 10.3978/j.issn.2095-6959.2019.09.023

Cite this article as: YANG Ziyao, DUAN Kenan, QIN Long, XIONG Jianxia, ZHANG Haitao, LIU Jing. Meta-analysis of the curative effect of ultrasound-guided percutaneous microwave ablation and thyroidectomy on the treatment of patients with papillary thyroid microcarcinoma[J]. *Journal of Clinical and Pathological Research*, 2019, 39(9): 1994-2003. doi: 10.3978/j.issn.2095-6959.2019.09.023