

甲状腺良性结节、微小癌及颈部转移性淋巴结热消融治疗专家共识(2018 版)

中国医师协会甲状腺肿瘤消融治疗技术专家组,中国抗癌协会甲状腺癌专业委员会,中国医师协会介入医师分会超声介入专业委员会,中国医师协会介入医师分会肿瘤消融专业委员会,中国抗癌协会肿瘤介入专业委员会,中国抗癌协会肿瘤微创治疗专业委员会

摘要:热消融作为肿瘤的治疗方法之一,已在多个实体脏器(肝脏、肾脏等)肿瘤领域取得令人满意的疗效。然而国内外对于其在甲状腺结节及颈部转移性淋巴结的临床应用中仍然有很大的争议。近几年国际上有多个相关学术组织发表了甲状腺结节的热消融治疗共识。国内 2015 年浙江省抗癌协会甲状腺肿瘤专业委员会也发表了“甲状腺良性结节、微小癌及颈部转移性淋巴结热消融治疗浙江省专家共识(2015 版)”。为进一步严格规范热消融技术在甲状腺肿瘤中的应用,由中国医师协会甲状腺肿瘤消融治疗技术专家组联合其他相关学术组织,多次组织专家研讨,几经易稿,初步达成共识,制定了“甲状腺良性结节、微小癌及颈部转移性淋巴结热消融治疗专家共识(2018 版)”。

关键词:结节性甲状腺肿;甲状腺肿瘤;消融技术;共识;指南

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Expert Consensus on Thermal Ablation for Thyroid Benign Nodes, Microcarcinoma and Metastatic Cervical Lymph Nodes(2018 Edition)

Thyroid Tumor Ablation Experts Group of Chinese Medical Doctor Association, Chinese Association of Thyroid Oncology, Interventional Ultrasound Committee of Chinese College of Interventionalists, Tumor Ablation Committee of Chinese College of Interventionalists, The Society of Interventional Therapy of China Anti-Cancer Association, The Society of Minimally Invasive Therapy in Cancer of China Anti-Cancer Association

Abstract: As one of treatment options for cancer, thermal ablation has satisfactory effects on many types of solid tumors (such as liver and renal cancers). However, its clinical application for the treatment of thyroid nodes and metastatic cervical lymph nodes is still under debates in China and abroad. In 2015, the “Expert consensus on thermal ablation for thyroid benign nodes, microcarcinoma, and metastatic cervical lymph nodes (2015 edition)”, was released by the Thyroid Cancer Committee of Zhejiang Anti-Cancer Association. To further standardize the application of thermal ablation for thyroid tumors, the Thyroid Tumor Ablation Experts Group of Chinese Medical Doctor Association had organized many seminars and finally came to the consensus to formulate the “Expert Consensus on Thermal Ablation for Thyroid Benign Nodes, Microcarcinoma and Metastatic Lymph Nodes (2018 Edition)”.

Key words: nodular goiter; thyroid neoplasms; ablation techniques; consensus; guideline

近年来,甲状腺良性结节、甲状腺微小癌的发病率呈逐年上升趋势,手术仍然是甲状腺肿瘤,尤其是甲状腺癌的首选治疗方法^[1-3];借助影像技术引导的热消融(射频、微波、激光)治疗具有损伤小、恢复较快、重复性较好、美观效果更好且甲状腺功能保全更

佳等特点,近年来在部分甲状腺良性结节、部分低危甲状腺微小乳头状癌及颈部转移性淋巴结非外科手术中已有所开展^[4-9]。自 2016 年“甲状腺良性结节、微小癌及颈部转移性淋巴结热消融治疗浙江省专家共识(2015 版)”^[10]发布后,国内对甲状腺结节消融治疗产生了热烈的讨论^[9,11-13]。随着时间的推移和实践深入,为体现医学界对甲状腺热消融技术新的认识,国内相关专家经过反复讨论,基于甲状腺肿

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瘤诊治原则、医学伦理及浙江版共识基础,出台本共识,旨在进一步强化甲状腺结节及甲状腺肿瘤的诊疗规范,也进一步规范医学研究^[14,15]。

1 术前评估

甲状腺结节热消融治疗是一种体内原位灭活肿瘤以达到局部根治(热切除)的技术手段,因此,其手术前的肿瘤学评估应作为治疗的前置条件。所有患者术前均需穿刺活检获得满意的病理结果,推荐采用细针穿刺抽吸活检(FNA)行细胞学检查,细胞病理学报告推荐采用 Bethesda 报告系统;也可应用粗针穿刺活检(CNB)行组织病理检查。良性结节是指 FNA-Bethesda Ⅰ类,对于符合消融条件的恶性结节也需 FNA 明确诊断,便于术前患者知情并做出选择。

2 适应证与禁忌证

2.1 甲状腺良性结节

2.1.1 适应证

需同时满足 1~3 条并满足第 4 条之一者。

①超声提示良性^[16,17],细针穿刺活检细胞学病理 FNA-Bethesda 报告系统报告为 Ⅰ类,或术前组织学活检病理证实为良性结节^[18];②患者无儿童期放射治疗史^[19];③患者充分知情情况下要求微创介入治疗,或拒绝外科手术及临床观察;④同时需满足以下条件之一:(1)自主功能性结节引起甲亢症状的^[20];(2)患者存在与结节明显相关的自觉症状(如异物感、颈部不适或疼痛等),或影响美观,要求治疗的;(3)手术后残余复发结节,或结节体积明显增大^[17,18]。

2.1.2 禁忌证

符合下列任意一条即排除。

①巨大胸骨后甲状腺肿或大部分甲状腺结节位于胸骨后方(对无法耐受手术及麻醉者,可考虑分次消融或姑息性治疗)^[21];②对侧声带功能障碍;③严重凝血功能障碍;④重要脏器功能不全。

2.2 甲状腺微小乳头状癌

至今没有足够的循证医学证据证明热消融对原发性甲状腺微小乳头状癌治疗的有效性,故不推荐将热消融治疗作为甲状腺微小癌治疗的常规手段。本共识多数专家认为,在严格遵循相关法律法规、严

格遵循医学伦理和伦理审查流程,尤其是患者充分知情的情况下,对符合以下适应证的患者,不反对开展前瞻性临床研究,探索治疗的有效性和安全性,以明确热消融治疗是否适用于甲状腺癌的治疗及其治疗适应证,但开展此前瞻性临床研究的手术操作医生需具备副主任医师及以上职称,从事甲状腺消融治疗工作 2 年以上。

2.2.1 适应证

需同时满足以下 9 条。

①非病理学高危亚型^[22,23];②肿瘤直径 $\leq 5\text{mm}$ (对肿瘤四周均未接近包膜者可放宽至直径 $\leq 1\text{cm}$),且结节距离内侧面后包膜 $>2\text{mm}$ ^[24,25];③无甲状腺被膜受侵且无周围组织侵犯^[26-29];④癌灶不位于峡部;⑤无多灶性甲状腺癌;⑥无甲状腺癌家族史;⑦无青少年或童年时期颈部放射暴露史^[30,31];⑧无淋巴结或远处转移证据;⑨患者经医护人员充分告知后,仍拒绝外科手术,也拒绝密切随访的^[32]。

2.2.2 禁忌证

符合下列任意一条即排除。

①颈部或远处发现转移^[33,34];②癌灶短期内进行性增大(6个月内增大超过 3mm)^[35];③病理学高危亚型(高细胞亚型、柱状细胞亚型、弥漫硬化型、实体/岛状型、嗜酸细胞亚型)^[36-38];④对侧声带功能障碍;⑤严重凝血功能障碍;⑥重要脏器功能不全。

2.3 颈部转移性淋巴结

对于甲状腺癌患者首诊发现的淋巴结转移,外科手术清扫是标准的首选治疗方案,故明确反对首诊患者淋巴结转移采取消融治疗。但对已行规范性外科手术切除及颈淋巴结清扫术后再次出现淋巴结复发或转移的,国际上已有多个指南或共识提出了可考虑采取热消融治疗的方式来处理^[39]。本共识认为,外科治疗依然是甲状腺癌复发、转移性淋巴结的首选治疗,但对符合以下适应证的患者,在充分告知前提下,可选择热消融治疗^[40,41]。

2.3.1 适应证

颈部转移性淋巴结需同时满足以下条件。

①根治性治疗后,颈部淋巴结再次复发转移的;②影像学提示转移性,FNA 证实转移性淋巴结;③经评估,患者存在手术困难且自身条件不能耐受外科手术或患者主观意愿拒绝外科手术的^[9,42];④转移性淋巴结碘¹³¹治疗无效或患者主观意愿拒绝碘

131 治疗的;⑤转移性淋巴结能够与大血管、重要神经分离且有足够安全的操作空间^[42]。

2.3.2 禁忌证

符合下列任意一条即排除。

①病灶位于 区的转移性淋巴结,其病灶对侧声带功能不正常^[9];②严重凝血功能障碍;③重要脏器功能不全。

3 术前准备

①患者进行相应体格检查,询问病史,有心脑血管疾病及糖尿病者,术前应积极治疗基础疾病,调整身体状况。②术前检查血常规、血型、尿常规、大便常规、凝血功能、传染病、肿瘤标志物、甲状腺功能 8 项、PTH、降钙素、生化全套、胸部 X 线片、心电图、肺功能、喉镜、颈部增强 CT 或 MR、超声造影(推荐超声造影检查,不做强制要求)等。③充分告知患者或其法定代理人患者疾病情况、治疗目的、治疗风险、当前治疗现状和替代治疗方法,并术前签署知情同意书。④患者术前、术后均禁食 4h 以上,手术通常采用局部麻醉,根据患者的实际病情及实际疼痛耐受情况也可选择(或调整为)局部神经阻滞、静脉全身麻醉、针刺复合麻醉等,以便患者更好配合。⑤建立静脉通路,方便静脉给药。

4 操作方法

①术前对病灶行多角度、多切面超声检查,明确病灶的位置及与周围组织的解剖关系。根据病灶大小、位置制定治疗方案和热消融模式、程序^[43,44]。②取仰卧位、颈部过伸后屈,常规消毒、铺巾,超声引导下用麻醉药局部麻醉皮肤穿刺点至甲状腺前缘外周包膜。③根据病灶的位置,相应地在超声引导下以 2%利多卡因或其稀释液在甲状腺前包膜与颈前肌群间隙进行局部浸润麻醉及隔离,随后以生理盐水或灭菌注射用水 10~20ml(或加入 0.5mg 肾上腺素混合液)在甲状腺外包膜与颈动脉间隙、甲状腺后包膜与食管间隙、甲状腺与甲状旁腺间隙及甲状腺后包膜与喉返神经穿行区域、转移性淋巴结与周围组织间隙分离,形成安全隔离区域(可根据具体肿瘤的位置酌情掌握),以保护颈动脉、食管、甲状旁腺及喉

返神经等相邻脏器及组织免受损伤。④选取安全、较近的路径(穿刺路径应以峡部进针为主要路径,也可根据实际需要采取侧颈部进针的穿刺路径),在影像(推荐超声)引导下避开颈部血管、气管、神经等重要结构^[44,45]。⑤消融良性大体积病灶推荐使用“移动消融技术^[46]”,将病灶分为多个小的消融单元,通过移动热源,逐个对单元进行热消融处理,需确保病灶于三维上能实现整体热消融。对于小体积病灶或恶性病灶则可使用“固定消融技术”,将热源固定于病灶中持续将其热消融,并酌情考虑多点消融,恶性者需扩大消融以达到局部根治^[47]。⑥热消融(射频、微波、激光)功率输出一般需由小至大逐步调节,具体功率输出范围及启停时间需根据具体热消融选择形式、病灶大小、病灶周围毗邻、设备厂家推荐值等情况酌情控制^[48,49]。⑦当实时超声显示病灶完全被热消融产生的强回声所覆盖,停止热消融^[50];有条件的可在消融后再次行增强影像学(推荐超声造影)检查评估热消融情况,以判断是否消融完全^[51]。⑧热消融操作者资质:参照《肿瘤消融治疗技术管理规范(2017 版)》。

5 疗效评价

①可在消融前、消融中、消融后分别进行病灶的影像学检查,推荐以超声影像学检查(超声造影更佳)作为消融术后即刻和消融术后随访疗效的主要评价指标^[52]。②热消融治疗后 3、6、12 个月随访行影像学检查观察治疗病灶坏死情况,病灶大小,计算体积及结节缩小率。治疗病灶缩小率:[(治疗前体积-随访时体积)/治疗前体积]×100%。③记录症状改善情况、相关并发症及其治疗、恢复情况。甲状腺肿瘤及其颈部转移性淋巴结热消融患者随访时需检测甲状腺功能指标及相应标志物等^[53]。④有条件的医疗单位可考虑术后(一般在术后 1~3 个月以后的复查过程中)通过穿刺病理检查判断疗效的确切性。

6 注意事项

①如患者在热消融过程中不能忍受疼痛或有明显不适,应减小消融功率或暂停消融,或改变麻醉方式,必要时分次消融^[54]。②术中需监护并密切观察患

者的心率、血压、血氧饱和度等生命体征。③因肿瘤较大或其他因素,部分患者可能存在消融不完全,可能需要多次或分次消融,部分患者甚至需要中转开放性手术;由于肿瘤的特殊性,消融后仍存在肿瘤复发增大的可能,术后需定期复查随访。④术前与患者及其家属或其法定代理人做好充分沟通,规范告知,使其充分知情,并术前签署知情同意书。

7 热消融术后并发症及处理

7.1 出血

由于大部分消融本身具备凝血功能,故术后出血发生率较低,出血多发生在腺体表面,少数在腺内或囊内;在穿刺过程中伤及皮下血管极少数可引起皮肤瘀斑。部分出血可通过热消融凝固止血,对于已经形成的血肿,可通过超声进行动态观察,并通过局部压迫的方法控制出血进一步发展。出血控制后,酌情加压包扎、冰敷防止再次出血,一般血肿会自行吸收^[55]。罕见情况如出血不能控制,尤其影响呼吸的时候需及时手术减压处理。

7.2 疼痛

少部分患者术后会出现轻微痛感或放射痛,大部分患者可耐受,随着时间的延续逐渐减轻^[56]。对于少数患者持续疼痛,需进一步查明原因,必要时通过暂停消融、追加麻药、颈丛神经阻滞等方法,进行针对性止痛、对症处理。

7.3 喉返神经和喉上神经损伤

热消融操作不当或肿瘤粘连可损伤喉上神经和喉返神经,部分为热消融过程中,热量通过甲状腺肿瘤及其周围组织传导,引起喉返神经、喉上神经灼伤或热损伤。喉返神经损伤常引起同侧声带麻痹,有时单侧声带麻痹没有任何症状,但大多数单侧声带麻痹的患者伴有声音的症状,从较轻的声音容易疲劳到比较严重的声音嘶哑。通常随着时间的延续患者症状逐渐减轻,绝大多数患者在3~6个月内恢复,可予以激素、神经营养药物等。双侧喉返神经损伤、呼吸问题可导致严重的上呼吸道梗阻,常常需要紧急气管切开或者紧急气管插管。喉上神经外支受损主要导致环甲肌麻痹,患侧声带张力减低,发声时可出现音调降低、音域变窄、嗓音低沉无力、最大发音时间缩短、无法高声言语或呼喊等音质改变。

7.4 肿瘤未控

由于肿瘤的特殊性,或术中出现不可预知的情况包括并发症等,导致消融手术失败,部分情况可能需及时中转或择期外科手术。(另注:这种情况下,为减少局部粘连,对于不影响生存期和生活质量的择期手术,建议考虑在消融术后3个月之后再行外科手术。)

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李新营	李志辉	卢漫	罗渝昆	秦建武
秦华东	邱新光	谭卓	唐丽娜	王朝晖
王淑荣	王小平	吴高松	谢晓燕	徐海苗
徐辉雄	殷德涛	余济春	余建军	詹维伟
张福君	张俊清	郑荣琴	郑向前	郑元义
朱又华	邹英华			

秘书:王一凡 王佳峰

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