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Hyperthermia in Combination with Radiation versus Radiation Alone for Superficial Tumors: A Systematic Review and Meta-analysis

Sicong Wang[1]†, Yanglong Wu[2]†, Congcong Wu[1]*

[1]The Second Affiliated Hospital and Yuying Children's Hospital of Wenzhou Medical University, Wenzhou 325000, Zhejiang, China

[2]Wenzhou Medical University Renji College, Wenzhou 325000, Zhejiang, China

† These authors contributed equally to this work and share the first authorship.

**Corresponding author: Congcong Wu, 690965785@qq.com*

Abstract: *Objective*: Aim to evaluate the efficacy of hyperthermoradiotherapy (HTRT) VS radiation therapy (RT) alone in patients with superficial tumors, mainly including breast cancer, head and neck cancer, and melanoma. The study undertook a systematic review and meta-analysis, and a preset subgroup analysis. *Methods*: A systematic literature search was conducted of the PubMed database and the bibliographies of related studies. *Results*: A total of 15 articles (n = 1368) met our eligibility criteria. The meta-analysis of all patients in 19 groups from 15 articles showed HTRT with significant improvement in complete response (CR) versus the RT group (*OR* = 2.393, 95% *CI* 1.749–3.274, p = 0.000) with high heterogeneity (χ^2 = 33.67, p = 0.014, I^2 = 46.5%). *Conclusion*: HTRT have significant improvement in CR versus RT alone in superficial tumors. A well-researched but maybe underutilized method, HT can have a major clinical impact by improving local tumor management.

Keywords: Hyperthermia; Radiotherapy; Superficial tumors; Complete response; Breast cancer; Local recurrence; Head and neck cancer

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1. Introduction

In the endeavor to augment tumoral temperature within the delineated interval of 40°C to 44°C, hyperthermia (HT) emerges as a potential efficacious therapeutic avenue. A high dosage of radiation therapy (RT), often requisite for maintaining local control, inherently carries an augmented likelihood of complications. HT enhanced the response to X-rays and photons in a murine tumor and normal skin with DNA damage and tumor hypoxia [1]. Tumors' alpha/beta ratios witness reduction attributable to thermoradiobiological interactions impacting reparative

processes post RT-induced genotoxic insults, established as pivotal predictors discriminating risk variances between hyperthermoradiotherapy (HTRT) versus standalone RT [2]. In low-pH, hypoxic or nutrient-deprived conditions where radiation resistance could be observed in common, HT can bring direct cytotoxicity to gross tumors. HT causes protein denaturation as the predominant target, which could induce damage to all intracellular signaling pathways, including DNA repair and cell cycle sensitivity [3,4]. Combined radio(chemo)therapy and HT stabilized or improved the assessment of quality of life scale items 3 and 12 months after treatment in patients who were treated with palliative intent and curative intent [5]. Multimodal treatment has been suggested to improve outcomes in retroperitoneal soft tissue sarcoma, and multimodal neoadjuvant therapies, including regional HT are not related to postoperative morbidity [6,7]. Superficial water-filtered infrared-A radiation HT has high efficacy in clinical oncology when exposed to composite tissues with highly variable water and fat contents [8]. Abundant clinical investigations have documented that HTRT amplifies clinical outcomes—manifested through bolstered response metrics, localized dominance, and enhanced survival indices among patients with breast, cervix, head and neck cancers, melanoma, bone metastases, portraying negligible increments in normal tissue morbid sequelae [9–13]. HT offers a cost-effective approach to cancer treatment, making it particularly suitable for resource-limited settings. Its relatively low equipment and operational costs, compared with advanced radiotherapy or surgical interventions, enable wider accessibility in underdeveloped regions. Considering the basic research evidence, good clinical performance, and low economic burden of HT, we have decided to further study HT.

It is discernible that properly achieving thermal elevation in relatively surficial lesions appears plausible, accompanied by adequate acquisition of temperature distribution measurements, even amidst constraints posed by extant HT apparatus; thereby, superficial cancer typologies are accordingly prioritized for investigational pursuits. Aiming to evaluate the efficacy of HTRT VS RT alone in patients with superficial tumors, mainly including breast cancer, head and neck cancer, and melanoma, the study instituted comprehensive systematic review methodologies supplemented by meta-analytical assessment, complemented by prespecified subgroup dissections.

2. Methods

2.1. Search strategy

Compliant with the PRISMA standards, a comprehensive examination of literature within the confines of the PubMed database from the database's inception up to May 1, 2024, assessing the effects manifested by HTRT VS RT alone for superficial tumors. The keywords used were: HT, radiation, breast cancer, superficial tumor. The bibliographies of selected articles were also manually searched for any additional related reports.

2.2. Selection criteria

Studies had to meet the inclusion criteria, which were formulated as a priority. Firstly, 2-arm studies (randomized and non-randomized) treated superficial tumors with local HT and external radiation in the HTRT group versus RT alone as control. However, those using surgery and/or interstitial brachy therapy were excluded. Secondly, the present meta-analysis focused on studies that assessed the complete response (CR) rate. Thus, articles that did not provide data about CR were excluded. For articles with overlapping data from the same trial, we only included the most complete and recent article after analyzing all the data. The publication language was restricted to English.

2.3. Data extraction

The priority endpoint of concern was CR at the end of treatment, and all studies that reported CR after HTRT

or RT alone were considered. CR was defined as all target lesions disappeared and no new lesions appearing, extracted from every eligible article as the primary outcome in our research. Other extracted data included the first author, publication year, country, study design, accrual period, number of patients, age, follow-up, primary/recurrent disease, previous RT, RT dose, type of HT, HT-RT sequence and adverse events (AEs). The articles were extracted independently by two authors in case of discrepancy, and a consensus was reached between the authors.

2.4. Statistical analysis

The examination of the impact wielded by HTRT in contrast with RT upon CR necessitated computing the aggregated odds ratio (OR), alongside its associated 95% confidence interval (CI). An evaluation was conducted concerning a state of heterogeneity, which stood appraised through the implementation of both the χ^2 test and I^2 statistic. When heterogeneity was high ($I^2 > 75\%$), performing a random effects model was preferred. Subsequently, sources contributing to said heterogeneity underwent exploratory scrutiny via meta-regression analyses, in which potentially relevant factors examined individually were year of publication, country, RCT or not, number of patients, primary disease, previous RT, type of HT, interval between RT and HT, HT sessions per week, HT duration. Analyzed further were preplanned subgroup analyses, which encompassed three distinct subgroups: breast cancer, recurrent breast cancer, head and neck cancer. We performed the meta-analysis in Stata 14.0 software with the commands metan, metareg, and metabias.

3. Results

3.1. Included studies

A comprehensive examination yielded 1975 articles alongside a review of 26 bibliographical references relevant to the subject matter. Following the exclusion of studies not meeting eligibility parameters, an initial selection brought forth 29 articles. Observations revealed that four qualifying articles presented data derived from identical patient cohorts, necessitating reliance solely on findings supported by the most recent and updated datasets. Of these, two documents failed to provide pertinent data, while eight exhibited inappropriate experimental design. It is discernible from this sequence that ultimately, 15 articles (sample size: $n = 1368$), spanning publications from 1987 through to 2008, conformed to our stipulated criteria for inclusion in analysis. Details of the study screening are presented in **Figure 1**. Study characteristics extracted from each study are separately summarized in **Table 1**.

Table 1. Features of the 15 articles

Author, year	Country	RCT	Accrual period	Number of patients	Age (years)	Follow-up	Primary/recurrent disease status	Pathology	Previous RT	Previous RT dose
Scott et al. 1984 [14]	USA	No	NA	59	Average 59.4	Minimum 6 months	18/59 patients with squamous cell carcinoma of head and neck; 39/59 patients with adenocarcinoma of breast cancer; 2/59 patients with melanoma		0	NA
Dunlop et al. 1986 [15]	UK	No	NA	28	Female 33-82, male 29-70	NA	18/28 patients with adenocarcinoma of breast cancer		NA	NA
Perez et al. 1986 [16]	USA	No	1964–1984	164	NA	Minimum 6 months	Recurrent breast cancer	NA	75% patients > 50 Gy	
Howard et al. 1987 [17]	UK	No	NA	16	NA	4–31 weeks, mean 13 weeks.	6/16 patients with squamous cell carcinoma of the head and neck		NA	NA
Lindholm et al. 1987 [18]	Sweden	No	1980–1984	38	22-94, median 68	1–38 months	45/85 tumors: breast; 15/85 tumors: head and neck	66/85 tumors: adenocarcinoma; 12/85 tumors: squamous cell carcinomas	41/57 tumors (RT + HT); 16/28 tumors (RT)	24–70 Gy, median 49 Gy (RT + HT); 26–67 Gy, median 47 Gy (RT)
Arcangeli et al. 1987 [19]	Italy	No	1977–1984	55	NA	NA	81/119 tumours: squamous cell carcinoma of the head and neck; 39/119 tumours: melanoma		NA	NA
Egawa et al. 1989 [20]	Japan	Yes	1985–1987	92	20–82	1 month	33/92 patients with head and neck; 19/92 patients with breast; 24/92 patients with others	NA	18/44 (RT + HT); 15/48 (RT)	NA
Li et al. 1990 [21]	China	No	1980–1983	23	34–78, median 56	6–37 months	12 primary breast tumors and 52 recurrent tumors	NA	20/23 patients	40–65 Gy
Datta et al. 1990 [22]	India	Yes	NA	65	NA	18-28 months, median 21 months	Previously untreated squamous cell carcinoma of the head and neck		No previous RT	
Perez et al. 1991 [23]	USA	Yes	1981–1987	236	18–93	NA	97/236 patients with head and neck; 68/238 patients with breast or chest wall	84/236 adenocarcinoma; 75/236 squamous cell carcinomas	38% (RT + HT); 46% (RT)	50–60 Gy
Valdagni et al. 1994 [24]	Italy	Yes	1985–1986	41	37–84, median 61	4–80 months, median: 12 months (RT), 18 months (RT + HT)	Metastatic squamous cell lymph nodes of the head and neck		No previous RT	
Vernon et al. 1996 [25]	Europe and Canada	Yes	1988–1993	306	61 ± 13	Minimum 5 months	30/306 patients with primary breast cancer and 276/306 recurrent. MRC BrI: 30/30 primary disease.	NA	120/171 (RT + HT); 90/135 (RT). ESHO 56/56: recurrent disease with previous RT.	NA
Jones etc 2005 [13]	USA	Yes	1994–2001	108	Median 52.4 (RT + HT); 59.3 (RT)	NA	37/56 patients with breast/breast wall (RT + HT); 33/52 patients with breast/breast wall (RT)	NA	22/56 (RT + HT); 17/52 (RT)	NA
Wahl etc 2008 [26]	USA	No	1993–2005	81	26–70, Median 48	1–144 months, median 12 months	Locally recurrent breast cancer with previous RT	NA	100%	19.6–82G, median 60 Gy
Huilgol etc 2010 [27]	India	Yes	2005–2009	56	31–78. median 58	61.5% < 6 months (RT), 42.8% 6–12 months (RT + HT)	Head and neck cancer	NA	NA	NA

*Interval since the last treatment (RT, surgery, chemotherapy, immunotherapy, HT)

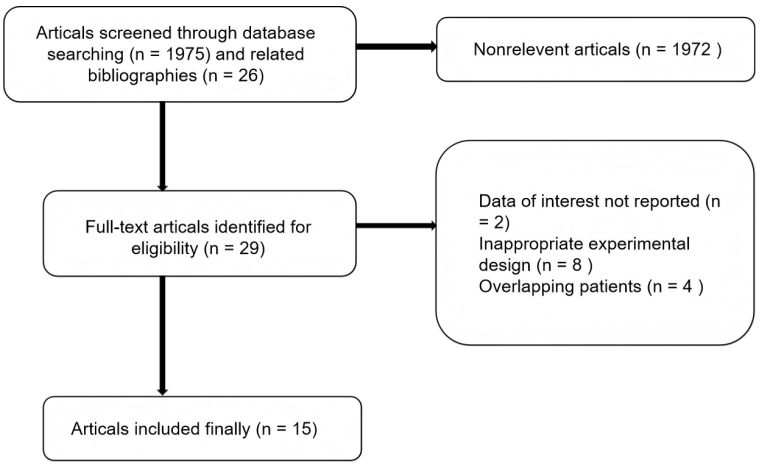

Figure 1. Flow diagram showing study eligibility and inclusion.

3.2. Metaanalysis

The meta-analysis of all patients in 19 groups from 15 articles showed that the addition of HT to RT resulted in significant improvement in CR versus the RT group (*OR* = 2.393, 95% *CI* 1.749–3.274, $p = 0.000$) with high heterogeneity ($\chi^2 = 33.67$, degrees of freedom (d.f.) = 18, $p = 0.014$, $I^2 = 46.5\%$; **Figure 2**). The application of the Egger test to individual trials did not reveal any publication bias (95% *CI* –0.810 to 3.604, $p = 0.199$; **Figure 3**). There was no factor that showed any significant relationship with heterogeneity in individual variable meta-regression analysis to explore the sources of heterogeneity (**Table 2**). We conducted three subgroup analyses in accordance with intended subsets and there was significant improvement in CR at each group (*OR* = 2.170, 95% *CI* 1.424–3.306, $p = 0.000$, and $\chi^2 = 17.10$, d.f. = 11, $p = 0.105$, $I^2 = 35.7\%$ for breast cancer; *OR* = 4.980, 95% *CI* 2.595–9.554, $p = 0.000$, and $\chi^2 = 1.92$, d.f. = 3, $p = 0.589$, $I^2 = 0.0\%$ for recurrent breast cancer; *OR* = 2.994, 95% *CI* 1.487–6.030, $p = 0.002$, and $\chi^2 = 14.56$, d.f. = 6, $p = 0.024$, $I^2 = 58.8\%$ for head and neck cancer; **Figure 4**).

Table 2. Results of meta-regression analysis

Covariate	Coefficient	95% *CI*		P
Year of publication	0.011	-0.038	0.060	0.640
Country (Asian or not)	0.314	-0.498	1.127	0.426
RCT	-0.286	-0.990	0.418	0.403
Number of patients	-0.003	-0.009	0.002	0.228
Primary disease (totally head and neck cancer)	0.680	-0.343	1.704	0.179
Previous RT	-0.516	-1.543	0.512	0.298
Type of HT (MV)	-0.239	-1.128	1.081	0.650
HT after RT	0.138	-1.672	1.948	0.872
Interval ≤ 30min between RT and HT	0.172	-0.836	1.179	0.715
HT sessions (2/wk or not)	0.318	-0.564	1.199	0.454
HT duration ≥ 30min	-0.124	-1.781	1.532	0.876

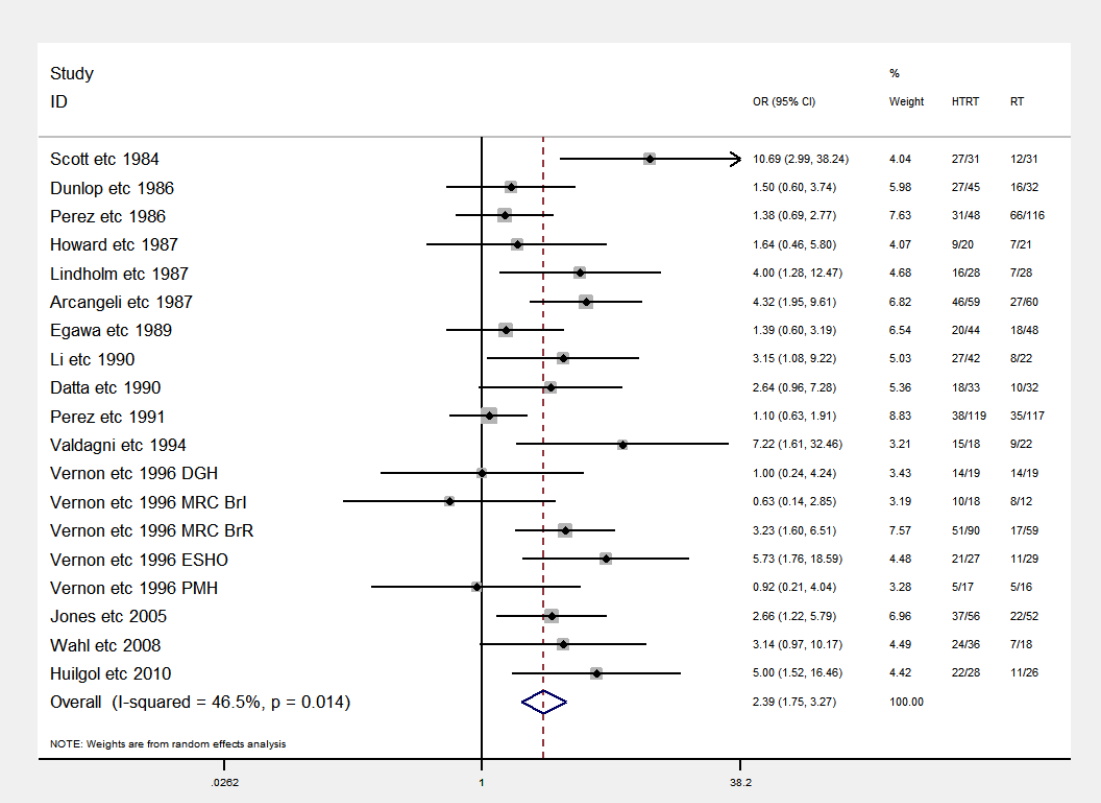

Figure 2. Forest plot of odds ratio (Hyperthermia + Radiation vs Radiation alone).Weights are from random effects analysis. Heterogeneity: I^2 = 45.4% (d.f. = 12), p = 0.029. The solid squares denote the mean difference, the horizontal lines represent the 95% confidence intervals (CIs), and the diamond denotes the weighted mean difference. Abbreviations: OR = odds ratio; HT = hyperthermia; RT = radiation therapy; d.f. = degrees of freedom.

* Complete response within 3 months of treatment.

** Complete response rates in the comparative study, including 56 tumors in 18 patients.

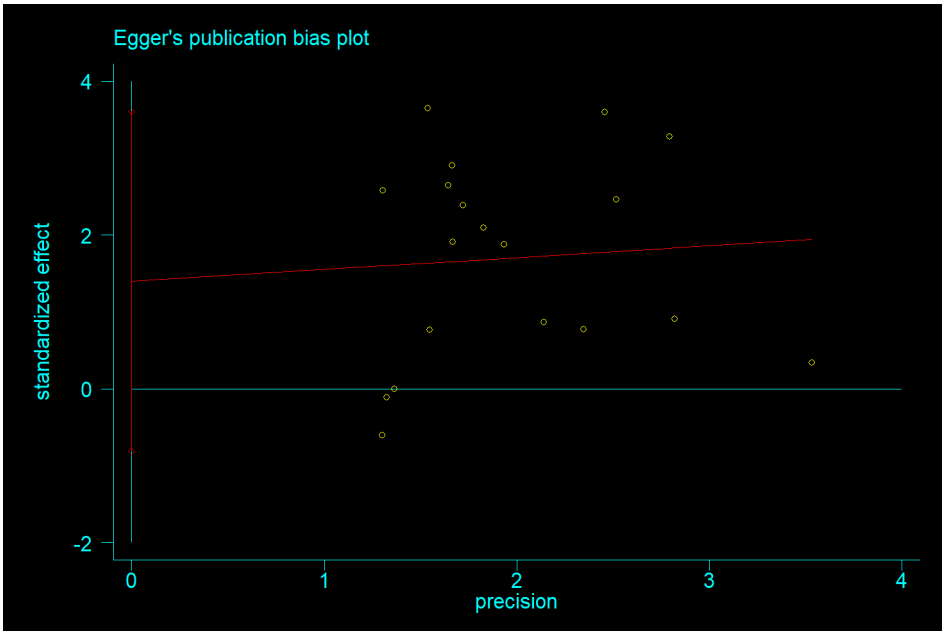

Figure 3. The Egger test for publication bias.95% confidence intervals (CIs): -1.445–3.550, p = 0.379.

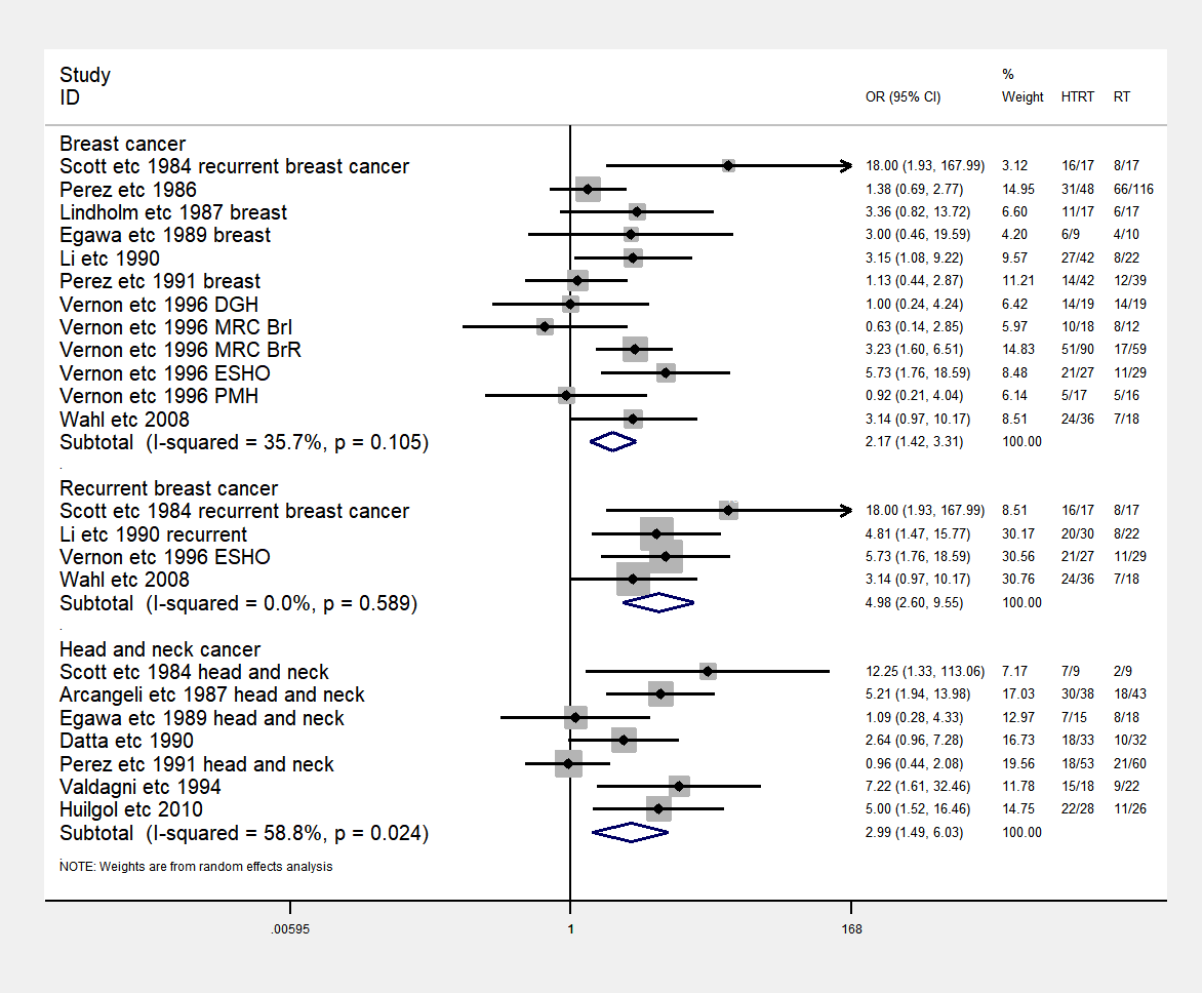

Figure 4. Forest plots of subgroup analyses based on different primary/recurrent disease status. Weights are from random effects analysis. Heterogeneity: breast cancer, I^2 = 35.7% (d.f. = 11), p = 0.105; recurrent breast cancer, I^2 = 0.0% (d.f. = 3), p = 0.589; head and neck cancer, I^2 = 55.9% (d.f. = 2), p = 0.104. The solid squares denote the mean difference, the horizontal lines represent the 95% confidence intervals (CIs), and the diamond denotes the weighted mean difference. Abbreviations: OR = odds ratio; HT = hyperthermia; RT = radiation therapy; d.f. = degrees of freedom.

3.3. Adverse events

By the overarching patient majority, both modalities of treatment were met with a level of tolerability not evoking substantial acute morbidity manifestations [24]. The combined therapeutics manifested local erythema, thermal blistering, facial oedema, and pain occurrences alongside cessation instances, generally grade 1 to 2 in severity, resolved through conservative interventions [13,15,22,23,25]. In patients treated by HTRT, instances of ulcerations appeared at a notable frequency (25% versus RT alone's 8%), and incidences of thermal burns were reported in 6% of thermally augmented recipients [16]. Observedly, 15/33 tumors exhibited third or fourth-degree integumentary reactions subsequent to administration of hyperthermic treatment via 2450 MHz microwave sans coupling water bag system, juxtaposed against 3/24 under the regimen involving 915 MHz microwaves with a coupling deionized water bag system and refinement of microwave applicators, as well as the temperature control system [18]. A discernible association emerges between the average maximum skin dose per treatment and the total skin reaction score [17]. Notably, late arousal effects on skin manifest as skin atrophy with depigmentation or pigmentation,

telangiectasia, and fibrosis present minimal differential expression relative to varying treatment regimens [23,25,27]. Furthermore, HT integrated post-RT retains acceptable tolerance without significantly increasing either the clinically meaningful acute or long-term toxicity over HT alone.

4. Discussion

This study demonstrated the value of HT as a strategy for improving radiation efficacy with little additional harm. Improved local control in lesions less than 3 cm with HTRT has been elucidated as germane to precise thermal application. The difference between the number of HT treatments was examined with negative results. The group with recurrent breast cancer in this trial, for whom full-dose extra radiation could hardly be given ($OR = 4.980$, $p = 0.000$, and $\chi^2 = 1.92$, $I^2 = 0.0\%$), showed the most striking clinical benefit from adjuvant HT.

The phenomenon of hypoxic cellular environments engendering radiation resistance stands corroborated. Moderate HT alters tumorous microecology via augmentative shifts in vascular permeability combined with escalated oxygen tension levels. Despite enigmatic nuances veiling its mechanistic underpinnings, synergy in heightening radiative cytotoxicity remains incontrovertibly acknowledged. Combined HT and re-irradiation may be considered as a definitive treatment option for unresectable radiation-associated angiosarcoma of the breast, or as an adjuvant treatment, particularly in cases with positive resection margins or following surgery for local recurrence [28]. HTRT provides long-term, high local control rates with acceptable toxicity for patients with recurrent, newly diagnosed, unresectable, or resected breast cancer at high risk of relapse [29]. A systematic review supports the beneficial role of regional HT in the treatment of high-risk soft tissue sarcomas [30]. In some series, deep regional HT combined with initial transurethral resection and cisplatin-based chemoradiation has improved 5-year overall survival rates by up to 20% in bladder cancer [31]. HTRT with or without chemotherapy can improve local control and survival in various difficult-to-treat cancers and adequate reconstruction of HT applicators for treatment planning can further improve treatment quality.

When combined with standard therapies such as radiation or chemotherapy, HT can enhance tumor control rates and improve patient outcomes. This affordability and adaptability not only address economic constraints but also help reduce disparities in cancer care, ensuring that more patients, regardless of their location, can benefit from effective, comprehensive treatment strategies. There were several limitations in this study. First, it was difficult to establish a heat-response link because the recommended heat treatments in the different experiments varied greatly. Second, our study lacked recent studies about HT, maybe because of a lack of attention to HT in the medical field. A well-designed prospective multicentric trial is warranted to further improve HT performance and promote this technology, especially in underdeveloped areas.

5. Conclusion

A well-researched but maybe underutilized method, HT can have a major clinical impact by improving local tumor management. Additionally, the use of HT in conjunction with RT and chemotherapy may become more significant in the anti-cancer therapeutic arsenal.

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The authors declare no conflict of interest.

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