EFFECTIVENESS OF INTEGRATED PROPHYLACTIC ANTIBIOTICS PRESCRIPTION IN PATIENTS UNDERGOING RADIOFREQUENCY AND MICROWAVE ABLATION OF LIVER TUMORS: A RETROSPECTIVE COHORT STUDY

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ABSTRACT:
An institutionalised in-house antibiotic prophylaxis (AP) guideline was developed in May 2019 to standardize AP prescription. This retrospective cohort study evaluated the effectiveness and clinical outcomes of the newly launched AP guideline on patients undergoing radiofrequency (RFA) and microwave (MWA) ablation of the liver from November 2018 to March 2020. Patients without high risk of biliary tree contamination were recommended a single dose of 2g IV cefazolin (or 600mg IV clindamycin in cases of beta-lactam allergy). Univariate analysis was conducted to evaluate the clinical outcomes.

The study included 87 patients who underwent 93 procedures consisting of 18 RFAs and 75 MWAs for liver tumours. Concordance with AP guidelines improved significantly (38.5% vs. 87.0%; $p<0.001$). There were no ablation-related infections and mortality within 30 days post-ablation, and post-procedural nausea and vomiting were significantly reduced (15.4% vs. 1.9%; $p=0.020$). No significant difference in post-procedural fever (7.7% vs. 5.6%; p-value=0.693), chest and/or abdominal pain (5.1% vs. 7.4%; $p=1.000$) were noted.

The newly implemented in-house antibiotic prophylaxis guideline streamlined AP prescribing in patients undergoing RFA and MWA. Additional research is needed to determine the effects on infection and mortality in patients with high-risk factors such as bile duct stents, sphincterotomies, and biliary-enteric anastomoses.

Keywords: Liver tumours, antibiotic prophylaxis, radiofrequency ablation, microwave ablation

INTRODUCTION

Over the past 3 decades, percutaneous hyperthermic ablation gained acceptance as the treatment of choice for patients with unresectable primary hepatocellular carcinoma (HCC) or liver metastases secondary to carcinoma due to its low morbidity rates(1). Radiofrequency and microwave ablations are hyperthermal ablation methods often associated with oncological applications; while other methods include laser and ultrasound(2). Radiofrequency ablation (RFA) creates coagulative necrosis by current-induced ionic friction in tissue that occurs at the targeted tumour and surrounding hepatic parenchyma(3), while microwave ablation (MWA) causes coagulative necrosis leveraging on the electromagnetic field to agitate water molecules(4). MWA is sometimes chosen as a favourable alternative to RFA for several reasons: it can achieve higher intra-tumoral temperatures to treat multiple lesions simultaneously, has no need for grounding pads, less susceptibility to the sink phenomenon, ability to work on larger ablation zones with shorter ablation times and possibly better local tumour control(5).

By inoculating the bloodstream or causing post-ablative tissue necrosis, hyperthermal ablation procedures are associated with the risk of infection(6). Similar rates of liver abscesses are observed in the RFA(1.8%) and MWA(1.6%) groups(7). The presence of biliary-enteric anastomoses, sphincterotomies, and bile duct stents can lead to contamination of the biliary tree, putting patients at high risk of infection(8). There has been no evidence that antibiotic prophylaxis is beneficial without these high-risk factors(9), but international guidelines for percutaneous interventional radiology recommend it due to the potential bacterial seeding in necrotic tissue(10). Antibiotics were prescribed in a heterogeneous manner to patients undergoing liver ablation. In May 2019, AP prescription guideline was standardised based on published evidence and international guidelines, following discussions with the Department of Vascular and Interventional Radiology (DVIR) and antimicrobial stewardship unit.

The primary objective of this retrospective cohort study was to determine the compliance with the new DVIR antibiotic prophylaxis recommendation, before and after implementation, and the effect that the new guideline has on patient outcomes. The secondary objective assessed the safety of the current antibiotic prophylaxis regimen to determine the need to revise the guidelines and improve antibiotic prophylaxis prescription.

METHODOLOGY

Study Population and Design

This was a retrospective review of the compliance and clinical effects of the newly implemented in-house DVIR antibiotic prophylaxis guideline in May 2019 for RFA and MWA. Duration of post-procedural AP was considered compliant if it was prolonged due to suspicion of infection. In the implementation period, measures were taken to improve the prescription of APs. In July 2019, a Computerised Decision Support System (CDSS) enhancement was introduced to aid doctors with AP prescriptions, and an internal roadshow was held in September 2019 to increase awareness of the new guideline and CDSS. An analysis of AP prescription implementation pre- and post-implementation periods from November 2018 to April 2019 and October 2019 to March 2020 respectively was conducted for this study.

Inclusion and Exclusion Criteria

All patients above the age of 21 who underwent imaging-guided RFA and MWA within the study period were included. Patients with either an infection or suspected to have an infection before the IR procedure, who were being treated with antibiotics not intended for prophylaxis prior to the procedure, who had DVIR procedures in conjunction with other surgical procedures, or who

had incomplete documentation of antibiotics, were excluded from the study.

Antibiotic Prophylaxis

2g of intravenous cefazolin was given prophylactically to all patients for its Gram-positive coverage for skin commensals such as *Staphylococcal and Streptococcal organisms* to reduce post-procedural infections(11). No oral or intravenous antibiotics were prescribed post-operatively. For patients with severe beta-lactam allergies, 600mg of intravenous clindamycin was prescribed; patients with high-risk factors received 1.2g of intravenous co-amoxiclav before the procedure, and 1g twice daily for five days following the procedure due to a greater risk of reflux cholangitis(12).

Data collection

Data was extracted from electronic medical records. All percutaneous liver ablation procedures were guided by computed tomography (CT), and their reports were stored electronically. Patient demographics and clinical characteristics collected included age, gender, weight, past medical history, hyperthermic ablation modality, number of tumour(s), maximum diameter of each tumour, prophylactic antibiotics regimen administered, and clinical and laboratory data for inflammatory markers.

Data Analysis

Univariate data analysis was performed using IBM SPSS 26.0 software package (SPSS, Inc., Chicago, IL, USA). Continuous variables were checked for normality using the Shapiro-Wilk test and analysed with the independent t-test. Categorical discrete variables were analysed using the Chi-squared ($\chi 2$) test or Fischer's exact test, where appropriate. All tests for significance were 2-tailed, and $p<0.05$ indicates statistical significance.

RESULTS

Demographics and clinical characteristics

We retrospectively analysed the data of 147 cases of RFA and MWA procedures during the study period. After applying the exclusion criteria, a total of 54 patients were excluded, including 4 patients who were on antibiotics treatment not intended for prophylaxis prior to the procedures, 11 patients who underwent ablation concurrently with other surgical procedures, and 39 patients who had incomplete documentation of the antibiotics prescribed (Figure 1). In total, 87 patients were included in this study. They underwent a total of 93 procedures, including 18 RFA and 75 MWA for 83 (89.2%) hepatocellular carcinomas, 9 (9.7%) liver metastases and 1 (1.1%) liver adenoma. Within the 93 cases of ablation, 70 (75.3%) had one tumour, 19 (20.4%) had two tumours and 4 (4.3%) had three tumours. Among these, 6 (6.90%) patients had undergone ablation twice, and 1 (1.1%) had high-risk factors of biliary-enteric anastomosis. The demographics and tumour characteristics of the two groups of ablation cases between pre-implementation (n=39) and post-implementation (n=54) are summarised in Figure 1. In terms of age, weight, gender, race, methicillin-resistant *Staphylococcus aureus* (MRSA) colonisation, prominent drug and past medical histories, no significant differences were observed between the two groups (Table 1).

Compliance to antibiotics prescribing

Types of AP prescribed to the patients and their compliance with the guidelines are shown in Table 2. Among patients who had their antibiotics regimen extended beyond the procedure (5 pre-implementation and 4 post-implementation), the duration of antibiotics prescribed was not significantly different between the 2 phases [6.4 ± 3.4 days (n=5) vs 7.3 ± 4.1 days (n=4), p=0.729]. Antibiotics prescription was prolonged for 2 (2.2%) patients who had suspected infections of unknown origin, 1 (1.1%) patient who had variceal bleeding, 1 (1.1%) patient who had hospital-acquired pneumonia, and 5 (5.4%) patients without any identified reason. In the post-implementation group, 44 patients (97.8%) followed the guidelines of 2g IV cefazolin,

markedly higher as compared to 12 patients (40.0%) in the pre-implementation group. Compliance with AP guidelines improved significantly (38.5% vs 87.0%; p<0.001); choice of antibiotics selected was more aligned with the guidelines post-implementation (43.6% vs 90.7%; p<0.001) but duration compliance was not significantly different (92.3% vs. 96.3%; p=0.646).

Clinical outcomes

Post-ablative symptoms, including fever, nausea, vomiting, chest pain, and abdominal pain within seven days of the procedure, as shown in Table 3. There was a significant decrease in post-procedural nausea and/or vomiting (15.4% vs. 6.4%; p-value=0.020). No readmissions or deaths related to RFA or MWA infections were identified within 30 days. There were no significant effects on post-procedural fever (7.7% vs. 5.6%; p-value=0.693), chest and/or abdominal pain (5.1% vs. 7.4%; p-value=1.000) or post-procedural hospitalisation stay in hospital (1.9 ± 1.4 days vs. 1.6 ± 1.4 days; p-value=0.372). Among patients with post-ablative symptoms (n=16), 4 (25%) patients had pro-calcitonin measured post-ablation, and none were elevated. Patient outcomes were not adversely affected.

DISCUSSION

There was a significant improvement in compliance with the standardised AP prescription guideline for RFA and MWA procedures. 87% of the patients were prescribed the appropriate choice of AP with the correct duration of prophylaxis, as compared to 38.5% before the implementation of the guideline. The significant increase in compliance of the new AP guidelines resulted in improved homogeneity of prescriptions for patients undergoing RFA and MWA from ceftriaxone and metronidazole to cefazolin. No significant clinical difference noted between both groups regarding clinical outcomes. No ablation-related infections or deaths were reported, and two (33.3%) of the re-admissions in the post-implementation group were due to post-ablation syndrome.

Infections of the surgical site are a leading cause of postoperative morbidity and mortality, considerably increasing the duration of hospitalisation and the cost of postoperative care(13). To decrease the likelihood of surgical site infections, timely administration of antibiotics perioperatively to establish adequate tissue and serum levels of antibiotics is vital(14). However, AP must be stopped within 24 hours of the procedure to prevent the emergence of resistant bacteria(15). Ceftriaxone and metronidazole were commonly used antibiotics, likely due to their indications extending to intra-abdominal infections(16). Even so, third-generation cephalosporins such as ceftriaxone can increase selection pressure for resistant bacteria with extended-spectrum beta-lactamase (ESBL) or AmpC beta-lactamase strains(17). Third-generation cephalosporins are also related to higher risks of *Clostridioides difficile* infection compared to narrow-spectrum first-generation cephalosporins such as cefazolin(18). While cefazolin has lesser gram-negative coverage (19), its ability to affect the skin flora has made it a desirable antibiotic due to the percutaneous nature of RFAs and MWAs(20).

Among the major complications associated with hyperthermic ablation, hepatic abscesses were the most significant infective complication reported in the literature (0.66%)(21). Symptoms include abdominal pain, fever, nausea, and vomiting, which can be fatal if left untreated(22). Level of serum procalcitonin (PCT) was tracked due to its specificity for bacterial infection(23) compared to levels of serum white blood cell count or C-reactive protein, which could be raised due to a systemic inflammatory response elicited by liver ablation procedures (24). It is important to note that symptoms of post-ablation syndrome often resemble those of post-ablation infection; consequently, further clinic imaging and laboratory testing are necessary for its

diagnosis(25). Our study showed no concurrent increase in serum PCT and positive blood cultures suggestive of infective complications in patients with post-ablation clinical symptoms. The newly implemented AP guidelines used in hyperthermal liver ablations did not adversely affect patient outcomes, and no liver abscesses or deaths resulted from the procedure. All patients who experienced clinical symptoms were discharged after close monitoring, and recoveries were uneventful.

There was a significant decrease in post-procedural nausea and vomiting in patients. One possible reason could be due to the choice of antibiotics used. Metronidazole was used commonly in conjunction with ceftriaxone prior to the implementation of AP guidelines. Since metronidazole is associated with a higher rate of nausea and vomiting (10-12%)(26) compared to cephalosporins (<4%)(27), omitting metronidazole from the new guidelines may have contributed to the reduction in incidences of post-ablation nausea and vomiting. Furthermore, combination antibiotics can increase the likelihood of adverse reactions (28).

This study had several limitations. Firstly, this was a retrospective study with a small sample size. Clinically significant conclusions about the effects of the newly implemented AP guidelines on post-ablation infection or mortality could not be drawn based on the small number of patients (n=87) included in the study. Secondly, a considerable number of patients were excluded due to incomplete documentation of the AP prescribed (n=39). Lastly, there was no standardisation in the measurement of laboratory data for inflammatory markers to trend baseline levels to that after ablation procedures in patients with suspected infections. It limited the parameters to analyse clinical outcomes of AP on post-ablative RFA or MWA.

CONCLUSION

Overall, the newly implemented in-house multipronged approach DVIR antibiotic prophylaxis guideline supplemented by electronic prescriptions and documentation improved AP prescribing in patients undergoing RFA and MWA. In the long run, maintaining ease of use and efficiency without compromising effectiveness is vital for sustaining the guidelines(29). There were no adverse effects in safety outcomes following single-dose IV cefazolin prophylaxis for RFA and MWA, and post-procedural nausea and vomiting associated with antibiotic use were reduced.

ETHICS

This retrospective study was approved by the ethics committee in the institution. Centralised Institutional Review Board (IRB) approval was sought (CIRB Ref. No. 2020/3142) and consent from participants was exempted.

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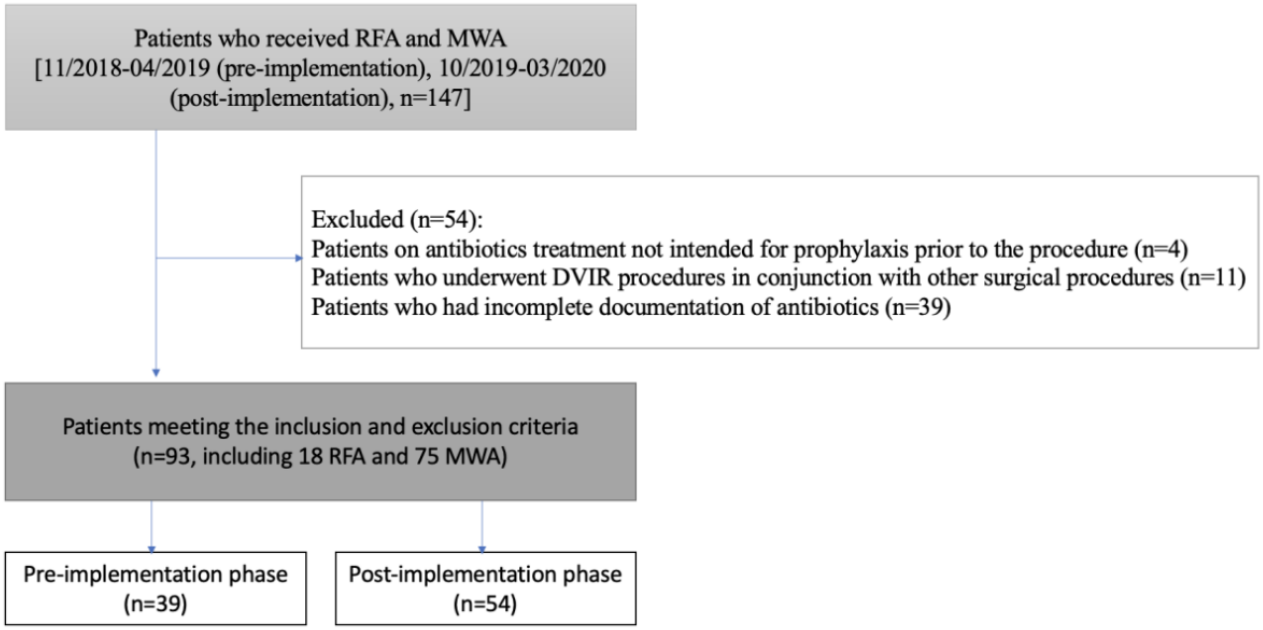
FIGURE LEGENDS:



RFA: Radiofrequency ablation; MWA: Microwave ablation; DVIR: Department of Vascular and Interventional Radiology

Figure 1: Flow diagram of study design

TABLE LEGENDS:

Table 1: Patient demographics and clinical characteristics

	Pre-implementation (n=39)	Post-implementation (n=54)	p-value
Age* (years)	69.5 ± 10.2	70.3 ± 9.9	0.698
Weight* (kg)	66.6 ± 13.2	66.6 ± 13.0	0.992
Gender (Male)	26 (66.7%)	39 (72.2%)	0.564
Race			0.838
Chinese	33 (84.6%)	45 (83.3%)	
Malay	2 (5.1%)	3 (5.6%)	
Indian	0 (0.0%)	1 (1.9%)	
Others	4 (10.3%)	5 (9.3%)	
Number of liver tumours per patient			0.086
Patients with one tumour	25 (64.1%)	45 (83.3%)	
Patients with two tumours	11 (28.2%)	8 (14.8%)	
Patients with three tumours	3 (7.7%)	1 (1.9%)	
Average of maximum diameter of liver tumour* (cm)	1.7 ± 0.7	1.6 ± 0.7	0.924
Diagnosis			0.302
Primary HCC	37 (94.9%)	46 (85.2%)	
Liver metastasis	2 (5.1%)	7 (13.0%)	
Liver adenoma	0 (0.0%)	1 (1.9%)	
Procedure done			0.810
MWA	31 (79.5%)	44 (81.5%)	
RFA	8 (20.5%)	10 (18.5%)	
Beta-Lactam allergy	8 (20.5%)	8 (14.8%)	0.472
Presence of high-risk factors	0 (0.0%)	1 (1.9%)	1.000
MRSA screen positive	2 (5.1%)	0 (0.0%)	0.173
Diabetes Mellitus	21 (53.8%)	32 (59.3%)	0.603
Chronic Kidney Disease	3 (7.7%)	5 (9.3%)	1.000
Chemotherapy in the past 30 days	0 (0.0%)	1 (1.9%)	1.000
History of TACE	6 (15.4%)	12 (22.2%)	0.410

*Data presented as mean ± standard deviation. HCC: hepatocellular carcinoma; MWA: microwave ablation; RFA: radiofrequency ablation; MRSA: methicillin-resistant *Staphylococcus aureus*; TACE: Transcatheter arterial chemoembolization

Table 2: AP prescription and compliance before and after implementation of AP guidelines

	Pre-implementation (n=39)	Post-implementation (n=54)	p-value
Patients with no MRSA, high-risk factors or beta-lactam allergy	30	45	<0.001
Cefazolin	12 (40.0%)	44 (97.8%)	
Ceftriaxone/Metronidazole	17 (56.7%)	0 (0.0%)	
Clindamycin	0 (0.0%)	1 (2.2%)	
Cefazolin/Metronidazole	1 (3.3%)	0 (0.0%)	
Patients with beta-lactam allergy ± positive MRSA	8	8	0.572
Clindamycin	5 (62.5%)	5 (62.5%)	
Ciprofloxacin/Metronidazole	2 (25.0%)	2 (25%)	
Ceftriaxone/Metronidazole	1 (12.5%)	0 (0.0%)	
Clindamycin/Metronidazole	0 (0.0%)	1 (12.5%)	
Patients with positive MRSA only	1	0	-
Cefazolin	1 (100%)	-	
Patients with high-risk factors only	0	1	-
Cefazolin	-	1 (100%)	
Compliance with AP choice	17 (43.6%)	49 (90.7%)	<0.001
Compliance with duration	36 (92.3%)	52 (96.3%)	0.646
Overall compliance with guideline	15 (38.5%)	47 (87.0%)	<0.001
Duration of extended antibiotics* (days)	6.4 ± 3.4	7.3 ± 4.1	0.729

*Data was analysed in 5 patients in the pre-implementation phase and 4 patients in the post-implementation phase; 4 (44.4%) patients with extended antibiotics were considered compliant to duration due to suspicion of infection. Data presented as mean ± standard deviation; MRSA: methicillin-resistant *Staphylococcus aureus*; AP: Antibiotics prophylaxis

Table 3: Comparison of post-RFA/MWA clinical outcomes

	Pre-implementation (n=39)	Post-implementation (n=54)	p-value
Fever (>38°C)	3 (7.7%)	3 (5.6%)	0.693
Nausea and/or Vomiting	6 (15.4%)	1 (1.9%)	0.020
Chest and/or Abdominal Pain	2 (5.1%)	4 (7.4%)	1.000
Post-procedure Hospitalization* (days)	1.9 ± 1.4	1.6 ± 1.4	0.372
30-day Re-admission	1	6	0.232
Post-ablation syndrome	0	2 (33.3%)	
Elective Admission	1 (100%)	0	
Other conditions	0	4 (66.7%)	
30-day Ablation-related Infection	0	0	-
30-day Ablation-related Death	0	0	-

*Data presented as mean ± standard deviation.