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A systematic review of recorded technical settings used in bipolar and monopolar transurethral resection of bladder tumors

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Abstract: High-frequency (HF) surgery has been established in medicine for decades and is very popular in transurethral (minimally invasive) surgery. However, the technical settings of generators are almost exclusively based on empirical data. So far, making a well-founded statement about a possible impact of technical parameters in HF surgery is nearly impossible. Therefore, the aim of this research was to systematically review the published data for transurethral resection of bladder tumor (TURBT) to find out, whether the publications consider both sufficiently, technical parameters and physical parameters. It is shown that although technical parameters are reported, they have been insufficiently considered in analyses so far. Further analyses must be performed.

Keywords: monopolar, bipolar, systematic review, bladder cancer, transurethral resection of bladder tumor (TURBT)

1 Introduction

To register and approve medical devices for the market, a considerable amount of globally different requirements must be met. However, one uniform requirement is having proof of product performance and safety for patients, users and third parties. In order to register medical products, providing this evidence is usually based on empirical data conducted in clinical or pre-clinical studies. However, empirical studies result in certain disadvantages: They are difficult to conduct, expensive and involve tests on humans. In many cases even significance can't be assured due to a lack of sample size. With this systematic review concerning readily available publications, the understanding of the relation between technical settings and operative outcomes shall be improved, thus minimizing the need for additional clinical studies.

Laparoscopic HF surgery shall be investigated as an exemplary surgery technique. Benefits from using HF current in surgery were already recognized decades ago [1]. Laparoscopic procedures are known to cause less blood loss as well as shorter healing duration and therefore shorter hospitalization time [2]. With bladder cancer incidence on the rise [3], TURBT is used as an exemplary medical field. The Guidelines on Non-muscle-invasive Bladder Cancer (NMIBC) estimate that around ¾ of primary diagnosed bladder cancers are non-muscle invasive [4]. It is known that the gold standard, still mostly performed with monopolar application (mTURBT), may be accompanied by complications for the patient. Therefore, bipolar application (bTURBT) is gaining more and more importance for this surgery type [5]. Published reviews and analyses have already addressed the comparison of bTURB(T) and mTURB(T).

Even though the usage of medical HF devices is well established, proof of performance and safety of HF generators and instruments is still insufficient, especially in regards of the used power settings. Specific power settings are often based on experience and tradition. Through testing, it was determined that microprocessor-controlled adaptation of energy transfers can achieve a minimization of tissue damage [6]. Therefore, it is assumed that the technical parameters (generator settings) in the field of HF surgery are crucial to prevent long-term consequences and complications and should not be ignored.

2 Materials and methods

2.1 Search strategy

A systematic search was conducted independently by 2 authors through the 3 electronic databases, consisting of PubMed, MEDLINE, and Cochrane collaboration Library, adhering to Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) statement [7]. Additional publications were considered which were suggested as

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"comment in", "similar articles" or "cited by" by the databases. References mentioned in the found articles were also considered. The last database search was performed on January 14th, 2022. Key words used for the search were: bladder cancer, TURBT, bipolar, monopolar, transurethral resection, electrocautery, HF surgery. Boolean operators were partially used to reduce or extend the results. No limitation of the publication date was used. Only publications with available full text in English were considered.

2.2 Data collection, analysis, and quality assessment

Standard PRISMA guidelines were pursued for this review. Two reviewers independently extracted information and did the quality assessment. The level of evidence (LE) of the included publications was assessed according to the Oxford LE Working Group [8] and was 2b for all studies and 1a for all review articles.

3 Results

3.1 State of the Art

Nowadays, many HF generators of the current generation no longer specify maximum power in Watts [W], but rather so-called effect levels. These microprocessor-controlled HF generators have been developed and make it possible to modulate current forms in an application-specific manner. Even though current-gen generators adjust their power level dynamically, it is still unknown to the public how these adjustments could affect surgery outcomes.

Typically, peri- and postoperative data, which are easily recordable without the patient having to undergo further examinations or requiring additional setups in the operating room, are documented during surgeries. These records are never fully comprehensive, and the success of surgery depends additionally on unrecorded (tissue type, pre-existing conditions, ongoing medications, thermal tissue properties like tissue hydration, temperature of used plasma) and unmeasurable factors (surgeon's experience). The outcome parameters were mostly subdivided into safety and efficacy. Safety is mostly defined by the parameters bladder perforation rate, transfusion needed, obturator nerve reflex rate and other occurring complications. Efficacy is described by operative time, catheterization time, and hospital stay. These parameters were published by nearly all studies included in this review paper. Therefore, this review considers only these outcome parameters, knowing that they are not fully comprehensive.

3.2 Included publications

804 publications were identified by overall research. After removing duplicates and publications without English full text, 242 publications were screened. 221 publications were excluded for not using HF, having insufficient content, lacking data or not being an RCT. Considered as eligible for this review were 21 full text. According to the PRISMA statement, a flow diagram describing the publication selection is shown in Figure 1.

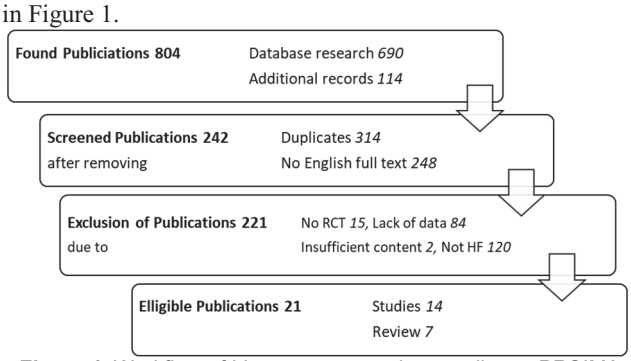

Figure 1: Workflow of Literature research according to PRSIMA.

3.2.1 Studies

Only RCTs which published primary data were considered. Studies were considered eligible if patients with bladder tumors underwent transurethral surgery (bTURBT and mTURBT) and surgical outcomes were recorded using different parameters. While extracting the characteristics of the 14 included studies, 2 of the studies were found to not report any technical settings and 1 study did report the voltage, but not power level. Likewise, 1 study did not publish any outcome parameters that could allow conclusions to be drawn about safety or efficacy. Therefore, only 10 of the 14 studies were considered further. The following information was extracted from all the 10 used studies: First Author, Year of Publication, Study Design, Patient Number, Devices used and Technical Settings (see Table 1). The results mentioned were extracted in form of: Operative time, Catheterization time, Hospital stay, Transfusion needed, Bladder perforation rate, Obturator nerve reflex rate (jerk).

3.2.2 Review Articles

Only review articles considering mTURBT and bTURBT were eligible for this review. The following information was

extracted from the 7 articles [19-25]: First Author, Year of Publication, Analyzed Parameters, Conclusion, Technical Parameters (see Table 1) and Compared Studies also mentioned in this Review.

Table 1: Included studies

Study	Type	Technical settings (cut/coag)	Number of Patients	Reported parameters[#]
[9] Monopoolar:	RCT	120 W / 80 W	42	A, B, C, D, E, F
Bipolar:		200 W / 120 W	48	
[10] Monopoolar:	RCT	70 W / 70 W	65	A, B, C, D, E, F
Bipolar:		70 W / 80 W	67	
[11] Monopoolar:	RCT	180 W / 60 W	21	A, C, D, E, F
Bipolar:		120 W / 80 W	23	
[12] Monopoolar:	RCT	90 W / 70 W	100	A, B, D, E, F
Bipolar:		100 W / 80 W	100	
[13] Monopoolar:	RCT	70 W / 70 W	40	A, D, E, F
Bipolar:		70 W / 80 W	40	
[14] Monopoolar:	RCT	70–90 W / 30–40 W	80	A, B, D, E, F
Bipolar:		160–200 W / 100–120 W	80	
[15] Monopoolar:	RCT	90 W / 70 W	79	A, B, D, E, F
Bipolar:		200 W / 120 W	75	
[16] Monopoolar:	RCT	90 W / 70 W	75	A, D, E, F
Bipolar:		100 W / 80 W	72	
[17] Monopoolar:	RCT	120 W / 60 W	50	A, B, C, D, E, F
Bipolar:		80 W / 80 W	50	
[18] Monopoolar:	RCT	120 W / 100 W	117	A, B, C, D, E, F
Bipolar:		200 W / 120 W	119	

[#] A: Operative time, B: Hospital stay, C: Catheterization time, D: Obturator nerve reflex rate, E: Bladder perforation rate, F: Transfusion needed

4 Discussion

Since 11 of the 14 found studies specify technical settings of the HF generator in the form of power [W], it can be assumed that the authors of the studies attach importance to technical settings. Incidentally, 3 authors were asked whether the technical values were documented, but so far, no answer has been received. All studies reporting technical values distinguished between monopolar and bipolar, as well as between cutting and coagulation. Since there are differences within these 10 studies in the general power setting range (30 W – 200 W), the technical parameters need to be looked at more closely. It is assumed that the technical parameters given were always the technical values set on the generator and not actually measured, as this measurement would hardly be possible within a surgery.

Except for 1 study, the 10 included studies reported outcome parameters, which were predefined to demonstrate safety and efficacy. Of the 10 studies that reported outcome parameters and published technical parameters, all reported operative time, 5 (+1)* reported catheterization time, 8 (+1)* reported hospital stay (efficacy). Regarding safety, all 10 studies report whether transfusions were necessary, the bladder perforation rate, and the obturator nerve reflex (jerk) rate.

One publication found consistently better results for bipolar application [13]. In this study the range of both energy levels was nearly identical (70 W monopolar, 70 W – 80 W bipolar). Here, it is striking that the power setting for both applications was low and thus may not have negatively influenced the outcome. However, it is worth noting that even with the same selected power setting, the effective amount of energy applied might differ due to the mode of application (mono- vs bipolar).

Seven publications did not report any significant differences in considered outcome parameters between monopolar and bipolar application (30 W – 180 W monopolar and 80 W – 200 W bipolar [9, 10, 11, 14, 15, 16, 18].

Other publications, however, found (partly) significantly better results in bipolar application for hospital stay [12] and resection time and obturator jerk [17]. The used power settings were 60 W – 120 W monopolar and 80 W – 160 W bipolar. Compared to the group without significant differences, the maximum selected power levels were lower for bipolar and lower for monopolar.

Only 2 of the 7 review articles mentioned technical parameters of the studies analyzed. No subgroup analysis was performed. 6 of the 7 review papers conclude that bipolar application is safer and/or more effective than monopolar. The conclusions are only based on the application technique, not on the used power settings. One paper exclusively cannot find any differences [23].

This wide range of findings also points towards the limitations of this review: There are only few papers covering HF surgery in this field and these only give few outcome parameters to work with. Another limitation which needs to be analyzed in more detail is that the published parameters regarding efficacy only indirectly provide evidence of whether the operation was truly successful. Finally, there is a blurring in the comparability of technical settings due to different generators and instruments used. Possibly more established operation techniques should be considered using HF surgery to make this blurring negligible due to large amounts of data.

*No values given but mentioned in publication

5 Conclusion

This systematic review shows that although technical parameters are reported in some studies, they have been insufficiently considered in analyses and reviews performed so far. Therefore, a meta-analysis not only considering physiological parameters but also including technical parameters must be performed. Only based on a statistical evaluation is it possible to recognize whether the outcome

parameters, which are intended to demonstrate the safety and efficacy of the surgery vary significantly with different technical settings. Since the reported differences are mainly based on the application techniques and not on the settings used, the two technologies should be considered separately.

Author Statement

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