



Safety of Cupping Therapy in Studies Conducted in Twenty One Century: A Review of Literature

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Authors' contributions

This work was carried out in collaboration between all authors. All authors designed the study and contributed to the protocol development. Author TS wrote the first draft of the manuscript which was revised a number of times by author NAQ. Authors TS, NAQ and IG managed the literature searches. All authors read and approved the final manuscript.

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Review Article

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ABSTRACT

Background: Cupping therapy is a well-known traditional treatment modality, and has been used in various diseases around the world since ancient times. This method is reported to have a better clinical as well as adverse events (AEs) profile as found in various studies conducted around the world.

Aim: This study identifies, assesses, and classifies the adverse events profile of various types of cupping therapies in studies conducted in twenty one century.

Methods: Using electronic and hand searches, three databases including Pub Med, Google Scholar and Cochrane library were searched from the year 2000 to 2016. Studies were included in this review provided they reported adverse effects related to cupping therapy. Observational studies were assessed using the WHO-UMC causality scale. Randomized controlled trials were assessed in accordance to the quality of reporting for harm data.

Results: Nine hundred seventy nine (n=979) articles were identified. Based on exclusion and

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inclusion criteria and extensive review of all retrieved articles by two independent reviewers, only 25 studies that included six RCTs, sixteen single case reports and three case series were finally selected. The mostly observed adverse events of cupping therapy were scar formation reported in four studies that described fifty nine cases, and burns reported in two studies described sixteen cases, respectively. The adverse events of cupping therapy could be classified into local and systemic adverse events.

Conclusion: Cupping therapy adverse events were infrequently reported, but they were not rare. Most of adverse effects were mild to moderate in severity. Some of the cupping therapy adverse events were preventable by following the general infection control guidelines, hygienic techniques, safety protocols and rigorous training of cupping therapists. Cupping adverse events should be reported in all studies on cupping, and this therapy should be practiced only by qualified medical professionals.

Keywords: Cupping therapy; cupping safety; single case reports; case series; randomized clinical trials; adverse events; Saudi Arabia.

1. INTRODUCTION

Cupping therapy is one of the oldest traditional therapies, and has been used in a variety of conditions by Egyptians, Chinese and Greeks since ancient times [1]. The oldest medical book Eber's papyrus written in 1550 B.C. had described cupping therapy [1]. Cupping therapy is done by creating a negative pressure inside cups either by suction or fire, which are applied to the affected skin area [2]. There are various types of cupping therapy, which include dry cupping, flash cupping, moving or massage cupping, wet cupping, and medicinal cupping [3].

Evidently, there are many uncontrolled observational studies including single case reports and case series supporting the efficacy of cupping therapy in various illnesses [4-25]. Furthermore, randomized clinical trials [26-31] and observational studies have increasingly evaluated the efficacy of cupping therapy in different medical conditions. Some of these studies have also reported the adverse events (AEs) of cupping therapy which are medical occurrences temporally associated with the use of a medicinal product, but not necessarily causally related. However, there are only few systematic reviews that have assessed the efficacy and adverse events of cupping therapy in some physical conditions including hypertension, low back pain, herpes zoster and others [32]. One of the caveats of these systematic reviews and studies was that the safety of cupping therapy was not examined satisfactorily. Similarly, the quality of reporting of AEs in studies evaluating the efficacy of cupping therapy was poor and needed further improvement [32]. Therefore, the authors report

a comprehensive review of literature with a focus on adverse events of hijama/cupping therapy.

2. AIMS AND RELEVANCE

The aim of this critical review was: to identify and assess adverse events of cupping therapy reported in the published studies conducted between the years 2000 to 2016. The relevance of this review is that it will impact the knowledge of traditional practitioners, and patients equally regarding cupping therapy which they think has no major adverse effects. This will also increase the awareness of the public about the safety issues of cupping therapy.

3. METHODS

3.1 Population and Design of Studies

The study population of this review included all studies done in humans that used cupping therapy as a key intervention regardless of patient age and condition. These studies that we targeted for this review were clinical studies including randomized clinical trials (RCTs or quasi -RCT), and observational studies including case studies and case series.

3.2 Inclusion and Exclusion Criteria

The inclusion criteria were; 1) studies published between the years 2000 and 2016 and full articles or abstracts were available, 3) studies involving all types of cupping therapies, methods of suction and cup types, and 4) cupping therapy was used as a key intervention. 5) Studies reported in detail the adverse events of the cupping procedure.

3.3 End Outcome

The main outcome of this review was to identify and classify the types of adverse events attributed to cupping therapy in studies conducted during the last one and half decades.

3.4 Procedures

Observational studies that used cupping therapy were assessed by using the WHO-UMC causality scale [33]. The quality of reporting of AEs in included RCTs was evaluated by using the CONSORT recommendation for harm data [34].

3.5 WHO-UMC Causality

WHO-UMC causality scale was used to assess cupping therapy in the observational studies. Furthermore, scoring of adverse events in included observational studies was as follows: 1) "certain" if there was plausible temporal relationship to cupping and could not be explained by other diseases or treatments and disappeared after cupping withdrawal, 2) "probable" if there was reasonable time relationship to cupping and unlikely to be explained by other diseases or treatments and reasonable relationship between cupping withdrawal and disappearance, 3) "possible" if there was reasonable time relationship to cupping and could also be explained by diseases or other treatments and unclear or missing information about cupping withdrawal and adverse events disappearance, 4) "unlikely" if there was improbable time relationship to cupping and adverse events explained by other diseases, 5) or "conditional" if adverse events occurred but there was need for more data and finally 6) "unclassifiable" if the report suggesting adverse event but cannot be judged because information is insufficient or contradictory [33].

3.6 Quality of Reporting of RCTs

Quality of reporting of RCTs was evaluated according to the CONSORT (Consolidated Standards of Reporting Trials) recommendation for harm data: 1) title or abstract stated the collection of harm or adverse events data, 2) the introduction stated the collection of harm or adverse events data, 3) list addresses definitions of adverse events related to cupping therapy, 4) describing adverse events collection or monitoring method, 5) describing plans for presenting and analyzing adverse events, 6)

describing any participants' withdrawal due to adverse events (AEs), and 7) providing the denominator for the analysis of harms. Scoring quality of reporting of RCTs was as follows; 1) adequate if described in details, 2) partially adequate if described but not in details, 3) inadequate if reported inadequately and 4) not reported if any item not reported at all [34].

3.7 Literature Search

The relevant literature published in English since the year 2000 was searched in PubMed, Cochrane Library and Google Scholar databases. The Boolean operators and keywords used in multiple electronic searches were cupping "AND" adverse events OR cupping, "AND" adverse effects OR cupping "AND" diseases. The search strategy and the keywords were modified as appropriate according to the searched database. In addition, the studies listed in review articles were hand searched. More than 900 articles (n=979) were retrieved, which were reviewed by two independent reviewers (NAQ & TS) and finally both agreed to include 25 published studies in this review.

4. RESULTS

There were 979 trials identified using electronic and hand searches. 951 were excluded through screening process which included reviewing titles and abstracts that did not meet inclusion criteria. Only 25 trials were finally selected and included in this review; six of them were randomized clinical trials, sixteen were single case reports and three were case series reports. Two of the authors independently reviewed all retrieved articles and agreed to include 25 articles for this review (Fig. 1 Prisma Chart).

4.1 Observational Studies

4.1.1 Analysis of single case reports

Sixteen single case reports were identified and included in this review for analysis. The most frequently reported AEs of cupping therapy were three cases of anemia [11,12,20], three cases of bullae [16,17,21]. The other single case studies that reported adverse effects of cupping therapy were: two cases of scar [4,7], two cases of Köebner phenomenon [23,25], and each one a case of hyperpigmentation [14], stroke [5], herpes simplex virus [10], cervical epidural abscess [13], cutaneous mycobacterium infection

[15], factitious panniculitis [18], lumbar abscess [22], lipoma [19], and acquired hemophilia [24]. Fourteen studies did not report on the practitioner type. Two studies reported qualified therapists [13,19], two studies reported doing cupping by patients themselves (auto-cupping) [18, 20] and one by unqualified therapist [11]. There was one case that used massage cupping [19], four patients used wet cupping [12,13,20,22], and fourteen cases used dry cupping method. In eleven cases, cupping therapy was used to treat various types of

musculoskeletal pains, and the most frequently reported musculoskeletal pain was the back pain in five case reports [7,11,14,21,22]. In other cases, cupping therapy was to treat cough [4], constipation [15], headache [13], skin conditions [23,25] and three case studies did not report the cause of using cupping therapy [5,16,18]. Causality between AEs and cupping therapy was scored as “probable” to “possible” in 15 cases and just one case was scored as conditional [5] (Table 1).

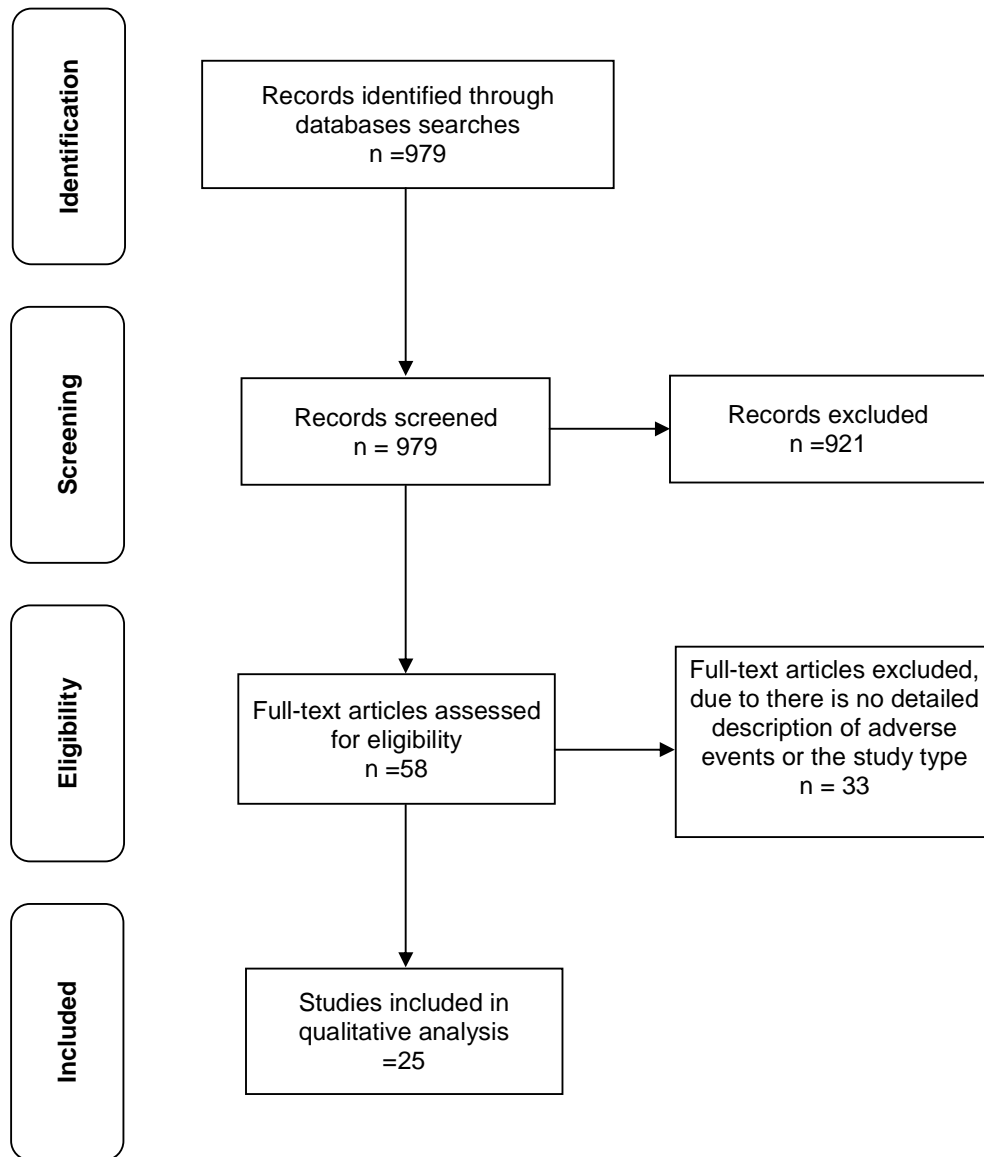


Fig. 1. Prisma chat

4.1.2 Analysis of case series studies

Three case series studies were identified and selected for analysis. Two of them were case series of AEs of cupping therapy [8,9] and one case series reported the efficacy of cupping therapy on fibromyalgia as well as its AEs [6]. The first case series study reported forty seven cases of skin lesions related to cupping therapy over a period of three years (2007-2009). These cases were collected from the outpatient department of National Institute for Health, Migration and Poverty, Rome (NIHMP) and Italian Dermatological Hospital in Ethiopia [8]. The second case series study reported fourteen patients who visited the First Hospital of Jilin University from October 2008 to August 2012 for the management of burn injuries induced by cupping therapy [9]. The third case series study reported two cases of burn among thirty patients of fibromyalgia who were treated with cupping therapy [6]. Cupping therapy type was not reported in the first case series study [8]. Dry cupping was the most prevalent type used (12/14, 85.7%) in second case series trial while Wet Cupping was used only by two patients (2/14, 14.3%) [9]. The third case series study used medicinal or herbal cupping. Bamboo cups were boiled in herbal decoction for 5 minutes and then were applied to the skin [6]. Causality between AEs and cupping therapy was scored as possible [8,9] and certain [6] (Table 1).

4.1.3 Analysis of randomized controlled trials

Six randomized clinical trials selected for this review were analyzed. Two RCTs did not report any AEs of cupping therapy [26,31]. The first RCT evaluated the effectiveness and safety of wet cupping therapy as a stand-alone treatment for the persistent nonspecific low back pain [NSLBP] [26]. The second trial evaluated the effectiveness, safety and feasibility of wet cupping therapy also for the persistent NSLBP [31]. The third RCT determined both the efficacy of wet cupping among patients with high blood pressure. This RCT also assessed the incidence of side effects in the intervention group. This RCT reported AEs of cupping therapy in every cupping session and frequency of therapy sessions. The reported AEs in decreasing frequency were headache (13 times), cupping-site pruritus (8 times), dizziness, feeling tired and sleepy after cupping (each 7 times), nausea (3 times), pain at cupping site (2 times). On the day of cupping therapy, one patient reported insomnia and another patient reported vomiting and hypotension (vasovagal attack) only one

time. A total of one hundred and ten cupping sessions were conducted. The only late AEs that persisted eight weeks after cupping treatment were reported by ten patients (out of 36 patients) who completed the follow up period were mild hyper-pigmented scars at the cupping site [27]. The fourth RCT investigated the effect of cupping pulsation therapy among 25 patients with chronic neck pain compared to standard medical care. The most frequently reported AEs were muscle soreness lasted for 24 hrs to 48 hrs (n=2), small hematoma at the site of cupping therapy lasted for two days (n=1), and increased neck pain lasted for one to five hours (n=2) [25]. The fifth RCT investigated the effect of cupping on neck pain among twenty participants, video display terminal (VDT) users compared to heat pad control. The most frequently reported AEs were skin laceration (n=1), whole body itching (n=1), pain at cupping site (n=1) [29]. The sixth RCT assessed the efficacy of a partner-delivered home-based cupping massage in 30 patients with chronic non-specific neck pain compared to progressive muscle relaxation for 12 weeks. Only one case reported increased muscular tension and pain [30]. Three RCTs were adequate to partially adequate for many items regarding the quality of reporting AEs [26,27,30] and another three RCTs did not report methods for presenting and analyzing AEs [28,29,31] (Table 2). The adverse events of cupping therapy could be classified into local and systemic events (Table 3).

5. DISCUSSION

In this review, twenty five studies were included by two independent reviewers for detailed analysis. The adverse events of dry cupping were most frequently reported followed by wet cupping. There were fifteen studies that reported AEs related to dry cupping, and eight studies reported AEs related to wet cupping. This finding did not support the results of Kim et al. [32] systematic review (2014), which reported more AEs of wet cupping therapy but not of dry cupping. Cupping therapy adverse events are rare events [32] is inconsistent with the present study. This might be due to the fact that Kim et al. [32] considered studies that were only conducted in Korea. The findings of the present review are congruous with Kim et al study; majority of cupping therapy adverse events were preventable, adverse events should be reported in detail in every study on cupping therapy, and cupping should be practiced by medical professionals.

Table 1. Single case reports and case series studies

Author	# of cases, (gender, age)	Reason for cupping	Cupping method	Practitioner	Cupping points	Adverse events	Causality
Birol et al, 2005, Turkey [4]	1(F, 36 Y),	Cough	Dry cupping	Not reported	Back	Keloid scar	Possible
Blunt & Lee, 2009 [5]	1(M, 5Y)	Not reported	DC using pump suction cups of 20 mm diameter.	Not reported	Posterior cervical area, anterior triangle of the neck, area between the mastoid process and angle of the mandible, and over the sternocleidomastoid muscles	Hemorrhagic stroke	conditional
Cao et al, 2011, Australia & China [6]	30 (Not recorded)	Fibromyalgia	Medicinal cupping	qualified	Ashi points	Burns	Certain
Chua et al. 2015, Singapore [7]	1(F, 70 Y)	Back pain	Dry Cupping , 1 session/ month for 30 years & moxibustion	Not reported	Back	Erythema abigne and scars	Possible
Franco et al. 2012 Italy [8]	47 (15F, 32 M, age not reported)	Not reported	Unidentified	Not reported	Unspecified (Back, sternum, and abdomen)	Hyperpigmented & skin scars & crusted lesions	Possible
Jing-Chun et al. 2014, China [9]	14 (5 F, 9M, 15-61 Y)	1 each of dog bite, tiredness, & mosquito bite & in 11pts no reason given	12 Dry Cupping and 2 wet cupping	2 unqualified & 1 qualified & in 11cases no info	Back (1case), forearm (2cases), & not reported (in 11 cases)	Burn	Possible
Jung et al, 2011, Korea [10]	1(F/56Y)	Pain and myalgia	Dry cupping & Acupuncture	Not reported	Left forearm	Herpes simplex infection	Possible
Kim et al. 2012, Korea [11]	1(F,77Y)	Low back and right leg pain	Dry Cupping , 30 sessions in 2 months	unqualified	Unspecified (anterior, posterior body trunk and both lower extremities)	Anemia and skin pigmentation	probable
Lee et al. 2008, Korea [12]	1 (M,39 Y)	Chronic musculoskeletal pain	WC for 6 months	Not reported	Whole back	Anemia	probable
Lee et al. 2012 Korea [13]	1(F,47 Y)	Headache	Wet Cupping & clean WC technique and acupuncture	Qualified	Posterior nuchal region (below level C2)	Cervical epidural abscess	probable

Author	# of cases, (gender, age)	Reason for cupping	Cupping method	Practitioner	Cupping points	Adverse events	Causality
Lee et al. 2014 Korea [15]	1(F,59 Y)	Constipation	Dry cupping	Not reported	abdomen	Cutaneous mycobacterium infection	Probable
Lee et al. 2014, Korea [14]	1(F, 26 Y)	Chronic back pain	Dry prolonged cupping	Not reported	Lower back	Hyperpigmentation	Probable
Lin et al. 2009, Taiwan [16]	1(M,55 Y)	Not reported	Dry Cupping for more than 20 minutes	Not reported	back	Iatrogenic Bullae	Probable
Mataix et al. 2005, Spain [17]	1(M,65 Y)	Polymyalgia rheumatica	Dry cupping	Not reported	Shoulder	Erythematous, bullous lesions, & hyperpigmentation	Possible
Moon et al. 2011, Korea [18]	1(F,56 Y)	Not reported or unidentified	Dry cupping	Self	Posterior neck and right shoulder	Factitious panniculitis	probable
Schumann et al. 2012, Germany [19]	1(F,65 Y)	Neck pain	Massage cupping	Qualified therapist	Back and shoulders	Lipoma	probable
Sohn et al. 2007, Korea [20]	1(F,66 Y)	Non specific pains	Wet Cupping for 10 years	Self	Not reported	Cardiac hypertrophy and anemia	Possible
Tuncez et al. 2005,Turkey [21]	1 (F,57 Y)	Back pain	Dry Cupping for over 40 minutes	Not reported	Lower back	Suction Bullae	probable
Turtay et al. 2014, Turkey [22]	1(M,51 Y)	Back pain	Wet Cupping	Not reported	back	Lumbar abscess	Possible
Vender & Vender, 2015, Canada [23]	1(M,45 Y)	Skin inflammation	Dry Cupping	Not reported	back	Köebner phenomenon	Possible
Weng & Hsiao, 2008, Taiwan [24]	1(F,58 Y)	Joint pain	Dry Cupping	Not reported	Left arm and thigh	acquired hemophilia	Possible
Yu et al. 2013, China [25]	1(M,40 Y)	Psoriasis	Dry cupping	Not reported	Back, chest, abdomen	Köebner phenomenon	Possible

Table 2. Randomized clinical trials

Author	Study description	Incidence by sessions and type of adverse events	Quality of reporting adverse events (CONSORT items for reporting adverse events)						
			1	2	3	4	5	6	7
Albedah et al. 2015, Saudi Arabia [26]	Evaluated the safety and effectiveness of wet cupping therapy in NSLBP*	No adverse events reported	Adequate	Partially adequate	adequate	Partially adequate	partially adequate	adequate	adequate
Aleyeidi et al. 2015, Saudi Arabia [27]	Determined the efficacy of wet-cupping for high blood pressure	Headache (13/110), pruritus (8/110), dizziness (7/110), feeling tired and sleepy (7/110), nausea (3/110), Pain (2/110) , insomnia (2/110), vasovagal attack (1/110), hyperpigmentation (10/40)	Adequate	Adequate	adequate	adequate	Partially adequate	adequate	Adequate
Cramer et al. 2011, Germany & Norway [28]	Evaluated the effect of cupping pulsation therapy on chronic neck pain compared to standard medical care	Short lasting muscle soreness (2/25), small hematoma (1/25) and increased neck pain (2/25)	Adequate	inadequate	Partially adequate	Not reported	Not reported	adequate	adequate
Kim et al. 2011, Korea [31]	Determined the effectiveness of wet cupping for NSLBP*	(0/21) No adverse events reported	adequate	inadequate	Partially adequate	Partially adequate	Not reported	adequate	adequate
Kim et al. 2012, Korea [29]	investigated the effect of cupping for neck pain related to VDT compared to heat pad control	skin laceration (1/20), generalized itching (1/20), and pain (1/20)	Adequate	Adequate	Partially Adequate	Partially adequate	Not reported	adequate	adequate
Lauche et al. 2013, Germany [30]	Evaluated the efficacy of 12 weeks of a partner-delivered home-based cupping massage compared to progressive muscle relaxation in patients with chronic non-specific neck pain.	Increased muscular tension and pain 1/30	Adequate	inadequate	Partially adequate	adequate	adequate	adequate	adequate

*NSLBP=nonspecific low back pain

Table 3. Classification of adverse events of cupping therapy

Local	Systemic
Scar formation	Anemias
Burn	Headache
Bullae formation	Dizziness
Abscess formation	Feeling tired and sleepy
Localized skin infections	Vasovagal attack
Hyperpigmentation	Nausea
Köebner phenomenon	Insomnia
Pain at cupping site	Whole body/generalized pruritus
Panniculitis	Acquired hemophilia
Pruritis at cupping site	
Skin laceration	

Evidently, the mostly observed AEs related to cupping therapy were scar formation [4,7,8,27], followed by burns [6,9]. The less frequently observed AEs were headache [27], pruritis at the site of cupping or whole body [8,27,29], dizziness [27], feeling tired [27], feeling sleepy [27], increase in pain, muscle tension or soreness [27,28,30], anemia [11,12,20], nausea [27], bullae formation [16,17,21], small hematoma or pain at cupping site [27-29], cervical and lumbar abscess formation [13,22], skin infection by herbs simplex [10] and mycobacterium [15], insomnia [27], and stroke [5], panniculitis [18], acquired hemophilia [24], lipoma [19], skin laceration [29], hyperpigmentation [14,27] and vasovagal attack [27]. The frequencies of these adverse effects were variable in these observational studies and RCTs. The implication of these findings is that the AEs profile of cupping therapy is relatively safe. However, AEs were frequently reported but they were short lasting.

According to this qualitative, critical review, the possible causes underlying preventable adverse events of cupping therapy were: 1) unqualified therapists, 2) not following infection control measures, 3) prolonged application of cups and 4) ignoring safety protocols. It is advisable that cupping therapy should be practiced by qualified and well trained medical professionals in aseptic conditions, cups should be applied for short time, and cupping sessions should reasonably be spaced. The randomized clinical trials that followed aseptic cupping technique and safety protocols did not report any adverse events [26, 31]. Most of AEs are preventable if safety protocols implemented in healthcare settings [35]. These preventive measures include but not limited to washing and disinfecting cups even if

intended to dispose, wearing personal protective equipment, wearing gloves and face shield if cups contaminated with blood when releasing pressure, using hazardous waste container to dispose contaminated materials and considering cupping procedure sequence with respect to personal protective equipment need [35]. It is also advisable to use single disposable cups [36] and disposable manual vacuum pump [37].

Furthermore, all RCTs concluded that there were no serious AEs related to cupping therapy, most of them were mild to moderate and disappeared shortly after [26-31]. Most of AEs were reported in single case reports and case series studies, which have level 4 evidence. These AEs were also mild to moderate and one AE was severe. Conversely, the RCTs have level 1/2 evidence; therefore according to this review cupping therapy is relatively a safe traditional therapy.

According to the AEs types identified in this review, the adverse events of cupping therapy could be classified into local and systemic effects. The local AEs were scar formation, burn, bullae formation, abscess formation, skin infections, hyperpigmentation, Köebner phenomenon, pain, panniculitis, pruritis and skin laceration. Systemic AEs attributed to cupping therapy were: anemia, headache, and dizziness, feeling tired, vasovagal attack, nausea, insomnia, whole body pruritis, lipoma and acquired hemophilia. Obviously, both adverse events equally affected locally and systemically human body. Therefore, researchers need to report these events comprehensively and systematically.

This review has some limitations including selection and publication biases. Despite extensive search of literature, some of the single case reports, case series and RCTs might have not been included especially those studies which were not accessible and without abstracts, and published in non-English medical journals. Other single case reports and case series often described by individual cupping therapists at their private websites were also not included in this review. We have no access to those observational studies, i.e., single case reports and case series and RCTs which were not published that might introduced publishing bias. The strength of this critical review is that we did a meticulous analysis of all studies conducted in twenty one century and reported most of adverse events and other related information of cupping therapy.

6. CONCLUSION

Cupping therapy adverse events were infrequently reported, but they were not rare, and most of them were mild to moderate. Majority of cupping therapy adverse events were preventable by following the general infection control guidelines, hygienic techniques, safety protocols and rigorous training of cupping therapists. Cupping adverse events should be reported in detail in all studies related to cupping therapy, and it should be practiced by qualified medical professionals. Overall, cupping therapy is a relatively safe traditional therapy with good adverse effect profile and used in numerous common chronic diseases worldwide. Further critical reviews that focus on adverse events of cupping therapy are required in future.

CONSENT

It is not applicable.

ETHICAL APPROVAL

It is not applicable.

COMPETING INTERESTS

Authors have declared that no competing interests exist

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