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Systematic review

Adverse events of miniscalpel-needle treatment in Korea: A systematic review

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ABSTRACT

Introduction: The miniscalpel-needle (MSN) acupuncture combines acupuncture and microinvasive surgery and is used extensively in China and Korea for the management of several painful conditions. Given the potential for this technique to cause damage to nerves and blood vessels, the aim of this systematic review was to investigate adverse events' (AEs) characteristics associated with MSN treatment in Korea, and summarize the reporting of safety procedural guidelines.

Methods: Nine electronic databases were searched. Clinical studies reporting MSN treatment associated AEs in Korea were selected by two independent authors. Severity and causality of each AEs was assessed. Safety precautions and infection prevention measures of each study were summarized.

Results: Of the 45 relevant studies included in this review, 15 reported adverse events. The quality of AE data was generally poor. Most AEs associated with MSN treatment reported mild symptoms (local pain having certain causality and grade 1 severity with highly heterogeneous incidence), while few reported moderate-to- severe and systemic AEs (headache, dizziness, or tiredness, having probable/likely causality and grade 2 or 3 severity). The checklist drafts of safety precautions and infection preventions consisting of 10 and 11 sub-items, respectively, were established.

Conclusions: Due to the high heterogeneity and poor quality of AE data, the definite characteristics of the AEs were undetermined. The heterogeneity may have occurred from differences in the strictness of AE report and safety procedural guidelines. To improve this, we summarized the drafts of safety procedural guidelines. Our findings could be used in further studies to establish MSN treatment safety.

1. Introduction

Acupuncture is increasingly used as a non-pharmacological method to treatment musculoskeletal pain. The miniscalpel-needle (MSN), a modern-type of acupuncture tool, is a needle with a flat knife at the tip (Fig. 1), which combines the effects of acupuncture and microinvasive surgery [1,2]. This modality was first popularized by professor Zhu in 1976 [3], and it is currently used extensively in Korea and China [4,5]. The term MSN is also used for acupotomy, miniscalpel-acupuncture, and needle-knife treatment [6]. Recent studies have shown that MSN treatment is widely used for the management of several painful conditions, including fibromyalgia, cervical spondylosis, and lumbar spinal stenosis [7–9]. This non-pharmacological treatment is not only associated with an improvement in pain conditions, but also a remarkable economic benefits. According to a report by the Chinese Academy of Sciences, an average of 360,000 people underwent MSN treatment daily, saving $ 8.7 billion in surgery costs [10].

A typical MSN has a 0.8-mm-wide blade combined with a 1-mm-diameter needle, which is thicker than the common filiform needle [11]. Because the blade constitutes the tip of the needle, the extent of invasiveness is greater than that with the common filiform needle. Therefore, the risk of adverse events (AEs) may be higher after MSN treatment than using the conventional needle, and concerns about damage to nerves and blood vessels by the blade-like structure have been raised [12,13]. However, the safety of MSN treatment has only been evaluated in case reports [14,15] and narrative review articles [12,16].

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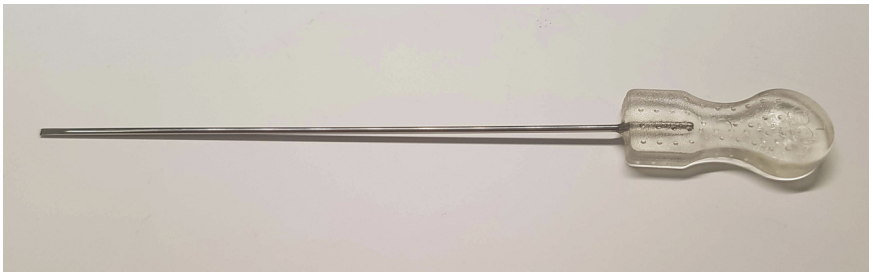

Fig. 1. Miniscalpel-Needle Treatment Tool.
0.8-mm-wide blade combined with a 1-mm-diameter needle (Dongbang Dochim, Dongbang Medical, Boryeong, Korea).

Likewise, MSN treatment may serve as a promising treatment option, especially in musculoskeletal pain, but the lack of safety data has limited its availability.

We therefore developed a protocol including Delphi study to define AEs caused by MSN treatment and to develop safety procedural guidelines considering the clinical settings in Korea [17]. As a part of the protocol, a systematic review investigating the incidence and types of AEs related to MSN treatment in Korea was planned.

Given the potential risks that may be associated with this technique a systematic review was conducted to investigate the characteristics including incidence, severity, and causality of AEs associated with MSN treatment in Korea and to summarize safety procedural guidelines reported in each study. Additionally, the final objective of this study was to use this data to develop a standardized AEs questionnaire and safety management guidelines following MSN treatment in Korea.

2. Materials and methods

The protocol of this review was published in an international academic journal [17].

2.1. Search strategy

The relevant literature was searched using nine medical databases (DBs), including three English DBs [Medline (via PubMed), EMBASE, and Cochrane Central Register of Controlled Trials (CENTRAL)] and six Korean DBs [Oriental Medicine Advanced Searching Integrated System (OASIS), Korean Traditional Knowledge Portal (KTKP), KoreaMed, Korean Studies Information Service System (KISS), National Digital Science Library (NDSL), and Research Information Sharing Service (RISS)]. Moreover, Google Scholar and the websites of seven relevant society journals, including *The Acupuncture*, *Journal of Pharmacopuncture*, *Korean Journal of Oriental Physiology & Pathology*, *Korean Journal of Acupuncture*, *Journal of Oriental Rehabilitation Medicine*, *Journal of Korean Medicine*, and *The Journal of Korea CHUNA Manual Medicine for Spine and Nerves,* were manually searched. The search terms were as follows: “(in Korean) Dochim (도침),” “(in Korean) Chimdo (침도),” “acupotomy,” “miniscalpel,” and “mini-scalpel.” These terms were chosen on the basis of the results of our previous study, where we analyzed MSN terminologies (in review). The searches were conducted between June 26, 2017 and July 6, 2017. All articles published from the inception of the electronic databases to the search dates were evaluated. The references in each of the included articles were also reviewed.

2.2. Study selection

Articles meeting the following inclusion criteria were included in this review: clinical studies using MSN treatment as an intervention, including case reports/cases series, surveys, cohort studies, before-and-after studies, nonrandomized controlled clinical trials (CCTs), and randomized controlled clinical trials (RCTs), and clinical studies conducted in Korea. There were no limitations with regard to underlying diseases, age, sex, and language of the participants. Studies reporting AEs should have further analyzed the frequency and characteristics of each AE. Two authors (CY, SH) independently selected the studies, and any disagreement between them was resolved by discussion under the arbitration of the third author (JT).

2.3. Data extraction

Two authors (CY, SH) independently extracted basic information and relevant data from the included studies using a standardized extraction form. Extracted information included the publication year, conditions of participants, reports and comments regarding AEs, reports of AE severity and causality, methods used for AE data collection, coping strategies, and the type of practitioner involved. The descriptions of safety precautions and infection prevention measures were extracted from the method section of each study. Moreover, from studies reporting AEs, details of MSN treatment [based on the Standards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA) guidelines], including the manufacturer, MSN blade width and needle length, treatment points, depth of insertion, texture, total number of sessions, total treatment duration, and the use of adjunctive treatments, were extracted [18].

2.4. Quality assessment

We assessed the quality of AE data in the studies reporting AEs after MSN treatment using the method used in a previous study evaluating the safety of acupuncture in pregnancy [19]. According to this method, we answered the following questions: “*Was the definition of AEs given?”, “Was the method used to monitor or collect AEs reported?”, “Were the type and frequency of AEs in each group reported in detail?”, “Was the severity of AEs assessed?”, “Was the causality between acupuncture and AEs assessed?”, and “Were participant withdrawals or dropouts due to AEs described adequately?”*. The response for each question was marked as yes, no, or unclear by two independent authors (CY, SH). Any disagreement was resolved by discussion under the arbitration of the third author (JT).

2.5. Data analysis

2.5.1. Characteristics of AEs

The reported AEs were analyzed for severity, causality, and incidence. The Common Terminology Criteria for AEs (CTCAEs) scale was used to assess the severity of AEs [20]. Although this scale has been developed to assess the severity of AEs associated with cancer treatments, it is also widely used for other diseases and interventions [19,21–23]. Using this scale, we graded the severity of AEs on a 5-point scale as follows [20]. Severe adverse events (SAE) refer to grade 3 or higher AEs.

Grade 1: mild, asymptomatic or mild symptoms, clinical or diagnostic observations only, intervention not indicated

Grade 2: moderate; minimal, local, or noninvasive intervention indicated; limiting age-appropriate instrumental activities of daily living (ADL)

Instrumental ADL refers to preparing meals, shopping for groceries or clothes, using the telephone, managing money, etc.

Grade 3: severe or medically significant but not immediately life-threatening, hospitalization or prolonged hospitalization indicated, disabling, limiting self-care ADL

Self-care ADL refer to bathing, dressing and undressing, feeding self, using the toilet, and taking medications.

Grade 4: life-threatening consequences, urgent intervention indicated

Grade 5: Death related to AE

The World Health Organization-Uppsala Monitoring Centre (WHO-UMC) causality assessment system was used to assess the causality of AEs [24]. This system has been developed to assess the causality of AEs associated with pharmacological treatments, but it can be used for non-pharmacological treatments as well [19]. According to this system, we evaluated the causality of AEs using the following six causality terms [24]: certain, probable/likely, possible, unlikely, conditional/unclassified, and unassessable/unclassifiable.

Two independent authors (CY, SH) assessed the severity and causality of AEs. Any disagreement was resolved by discussion under the arbitration of the third author (JT).

Quantitative synthesis of the AEs incidence was not performed due to the heterogeneity of the studies included. The incidence of AEs in each study was analyzed by dividing by the number of participants and number of treatments by the number of AEs. Each frequency was presented as the incidence of AEs or SAEs per 1000 individuals and 1000 treatment sessions, with 95% confidence intervals (CIs).

2.5.2. Safety and infection prevention strategies

We summarized the safety precautions and infection prevention measures described in the included studies. In detail, the ratio of each subitem was quantified after division into the following categories: practitioner, imaging device, treatment procedure for safety guidelines, medical supplies, pretreatment infection prevention guidelines, and posttreatment infection prevention guidelines. Thus, we synthesized the strategies described in each study to create a checklist draft and used this draft to reassess adherence rates in each study.

3. Results

3.1. Description of studies

A total of 490 articles were identified. After the elimination of 303 duplicate publications, 187 were screened for their titles and abstracts. From these, 141 that did not meet the inclusion criteria were excluded. The full text of the remaining 46 articles was reviewed, and one that did not use MSN treatment as an intervention was excluded. Among the 45 included articles [25–69], there were two theses [35,56] (Fig. 2).

3.2. Study characteristics

The publication year varied from 2004 to 2016; clinical studies on MSN treatment have been actively published since the late 2000s. The 43 articles other than the two theses [35,56] were journal articles [25–34,36–55,57–69]. When the diseases of participants were classified by the International Classification of Diseases (ICD), the M code, which refers to diseases of the musculoskeletal system and connective tissues, was the most common (22 studies; 48.89%) [28,29,35,38,39,41–43,45,46,48,49,52,54,55,57,58,60,61,63,64,69], followed by the G code, which refers to diseases of the nervous system (15 studies; 33.33%) [29,30,32,26–34,36,37,44,50,56,62,65,66,68]. Only 15 studies (33.33%) reported AEs associated with MSN treatment [26,31,34,36,37,40,42,43,46,49,51,63,65,67]; three studies (20.00%) reported the AE severity [26,40,42] and two (13.33%) reported the AE causality [51,67]. In addition, 35 studies (77.78%) included descriptions of safety precautions [25,27,29–39,41–47,49–52,54,56–59,61–63,67,58–69] and infection prevention [25–27,29–39,41–45,47–51,54–56,58,59,62,64–67,69] measures (Table 1).

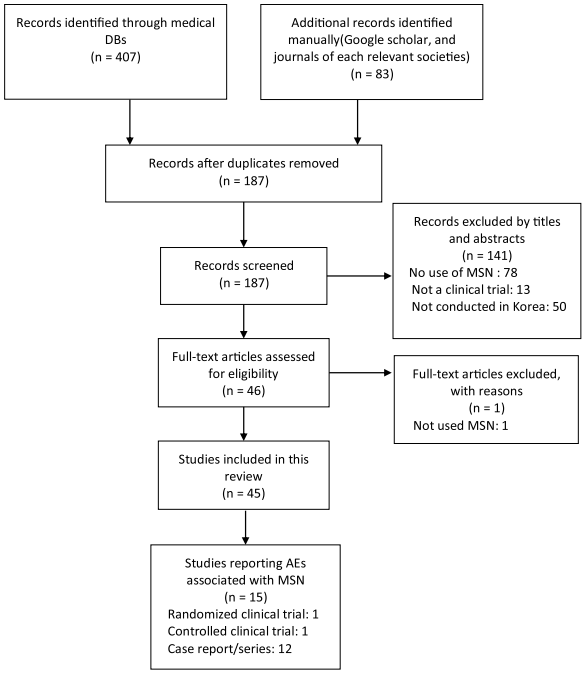

Fig. 2. PRISMA flow chart.

3.3. Analysis of AEs associated with MSN treatment

3.3.1. Treatment procedures

The needle used for MSN treatment in the 15 studies (304 patients) that reported AEs [26,31,34,36,37,40–43,46,49,51,63,65,67] was mostly manufactured in Korea. The blade width was 0.5–2.0 mm and the needle length was 50–80 mm. MSN treatment was performed at the lower back, neck, face, wrist, shoulder, upper arm, and abdomen, according to the target disease. The lower back was the most common treatment region (seven studies; 46.67%) [31,34,36,42,49,65,67], followed by the neck (five studies; 33.33%) [37,46,51,63,67]. The number of treatment sessions ranged from one to six. The most frequent number was six, and these sessions were performed over a period of 12 to 24 weeks (Table 2).

3.3.2. Characteristics of AEs

Twelve studies reported the number of patients with AEs [26,31,34,36,41,42,46,49,51,63,65,67]. In most cases, mild and local AEs such as needling pain, erythema, or ecchymosis were reported, whereas moderate-to-severe and systemic AEs such as headache, dizziness, or tiredness were reported in two studies. Local AEs were all reported in case reports or case series, and the incidences per 1000 individuals or 1000 treatment sessions showed a large variation from 0 to 1000. Furthermore, they were determined to have certain causality according to the WHO-UMC causality assessment system and Grade 1 severity according to the CTCAEs scale.

On the other hand, systemic AEs were reported in one retrospective study and one RCT. In the retrospective study, the incidences per 1000 individuals or 1000 treatment sessions of headache after MSN treatment were 123 [67], and they were assessed to have probable/likely causality according to the WHO-UMC causality assessment system and Grade 2 or 3 severity according to the CTCAEs scale. Meanwhile, the RCT reported occurrence of dizziness and tiredness in some participants

Table 1
Characteristics of and safety-related outcomes in studies on miniscalpel-needle treatment in Korea.

Author (year)	Condition	ICD code	Reports of AE	Comments about AE	Description of safety precautions	Description of infection prevention measures	Reports of AE severity	Reports of AE causality
Cho [35]	Cervical disc disorder with radiculopathy	M 501	N	N	Y	Y	NA	NA
Jang [31]	Lumbar intervertebral disorders with radiculopathy	G 511	Y	Y	Y	Y	N	N
Jang [29]	Achilles tendinitis	M 766	N	Y	Y	Y	NA	NA
Jang [27]	Postmastectomy lymphoedema syndrome	I 972	N	N	Y	Y	NA	NA
Jung [49]	Spinal stenosis, lumbar region	M 4806	Y	Y	Y	Y	N	N
Kim [59]	Sprain and strain of ankle	S 93	N	Y	Y	Y	NA	NA
Kim [58]	Shoulder lesions	M 75	N	Y	Y	Y	NA	NA
Kim [25]	Congestive heart failure with systolic dysfunction	I 5004	N	N	Y	Y	NA	NA
Kim [57]	Cervical disc disorder with radiculopathy	M 501	N	Y	Y	N	NA	NA
Kim [32]	Peroneal nerve palsy	G 573	N	Y	Y	Y	NA	NA
Kim [69]	Avascular necrosis of bone	M 87	N	Y	Y	Y	NA	NA
Kim [50]	Peroneal nerve palsy	G 573	N	Y	Y	Y	NA	NA
Kim [56]	Lumbar intervertebral disorders with radiculopathy	G 511	N	Y	Y	Y	NA	NA
Kim [45]	Rotator cuff or supraspinatus tear or rupture not specified as traumatic	M 751	N	Y	Y	Y	NA	NA
Kim [64]	Radiculopathy	M 541	N	N	N	Y	NA	NA
Kim [65]	Lumbar intervertebral disorders with radiculopathy	G 511	Y	Y	N	Y	N	N
Kim [66]	Lumbar intervertebral disorders with radiculopathy	G 511	N	N	N	Y	NA	NA
Kim [36]	Lumbar intervertebral disorders with radiculopathy	G 511	Y	Y	Y	Y	N	N
Ko [67]	NA (headache after MA)	–	Y	Y	Y	Y	N	Y
Kwak [44]	Lumbar intervertebral disorders with radiculopathy	G 511	N	Y	Y	Y	NA	NA
Lee [61]	Cervicalgia	M 542	N	Y	Y	N	NA	NA
Lee [60]	Primary athrosis NOS, knee joint	M 1906	N	Y	N	N	NA	NA
Lee [68]	Lumbar intervertebral disorders with radiculopathy	G 511	N	Y	Y	N	NA	NA
Lee [28]	Polyarteritis nodosa	M 300	N	N	N	N	NA	NA
Lee [37]	Facial palsy	G 510	Y	Y	Y	Y	N	N
Lee [42]	Spinal stenosis, lumbar region	M 4806	Y	Y	Y	Y	Y	N
Lee [46]	Cervical disc disorder with radiculopathy	M 501	Y	Y	Y	N	N	N
Lee [47]	Tears of medial and lateral menisci	S 8322	N	N	Y	Y	NA	NA
Lee [55]	Fibromyalgia	M 797	N	N	N	Y	NA	NA
Lim [30]	Carpal tunnel syndrome	G 560	N	Y	Y	Y	NA	NA
Lim [33]	Tarsal tunnel syndrome	G 575	N	Y	Y	Y	NA	NA
Lim [39]	Tennis elbow	M 771	N	Y	Y	Y	NA	NA
Min [26]	Scar NOS	L 905	Y	Y	N	Y	Y	N
Park [41]	Ganglion, wrist joint	M 6743	Y	Y	Y	Y	N	N
Park [52]	Sprain and strain of whiplash injury	S 134	Y	N	Y	N	NA	NA
Park [52]	Ossification of the posterior longitudinal ligament, cervical region	M 4882	N	Y	Y	Y	N	Y
Park [62]	Lumbar intervertebral disorders with radiculopathy	G 511	N	N	Y	Y	NA	NA
Park [48]	Primary athrosis NOS, knee joint	M 1906	N	Y	N	Y	NA	NA
Shin [63]	Myofascial pain syndrome, shoulder region	M 7911	Y	Y	Y	N	N	N
Sung [54]	Osteonecrosis	M 87	N	Y	Y	Y	NA	NA
Sung [34]	Lumbar intervertebral disorders with radiculopathy	G 511	Y	Y	Y	Y	N	N
Yoon [40]	Obesity	E 66	Y	Y	N	N	Y	N
Yuk [43]	Frozen shoulder	M 750	Y	Y	Y	Y	N	N
Yuk [38]	Spinal stenosis, lumbar region	M 4806	N	N	Y	Y	NA	NA
Yun [53]	Lumbar intervertebral disorders with radiculopathy	G 511	N	Y	N	N	NA	NA
Total (%)			15/45 (33.33%)	34/45 (75.56%)	35/45 (77.78%)	35/45 (77.78%)	3/15 (20.00%)	2/15 (13.33%)

Abbreviations: AE adverse event; ICD International Classification of Disease; NA not applicable (adverse event was not reported).
Note: The severity and causality of AEs were assessed using the Common Terminology Criteria for AEs and The World Health Organization-Uppsala Monitoring Centre causality assessment system, respectively.

Table 2
Details of the miniscalpel-needle used in the included studies: Tools and procedures.

Author (year)	Manufacturer	Blade width (mm)	Needle length (mm)	Treatment points	Depth of insertion (mm)	Texture indicating proper procedure	Total session number	Total duration	Adjunctive treatments
Jang [31]	HC	0.8	NR	Tender points of BL23, BL24, BL25, GV3, EX-B2	2/3 of the needle length	NR	3	20 days	ATx, PATx, C, medication
Jung [49]	N1:HC N2, N3:D	N1:0.8 N2:0.5 N3:1.0	N1:80 N2:80 N3:80	Lumbar transverse process Lumbar facet joints Yellow ligament (attachment area)	Level of bone surface	NR	1	NA	ATx, PATx, HM
Kim [65]	HK	1.2	60	Erector spinae	NR	NR	1-2	3-5 days	ATx, HM, P
Kim [36]	HK	1.2	60	Tender points of erector spinae	50–60	Pain & twinge (nerve stimulation)	3	2 weeks	ATx, HM
Ko [67]	D	L-spine:1.1 C-spine:1.0	L-spine:75 C-spine:50	1. Yellow ligament 2. Lumbar facet joints and erector spinae	1. Level of yellow ligament (40–70) 2.20–30	NR	NR	NR	NA
Lee [37]	D	0.5	50	*	Level of bone surface (40–80)	NR	3	12-15 days	ATx, PATx, HM
Lee [42]	D	1	80	Lumbar facet joints	Level of bone surface	Pain and twinge (nerve stimulation)	1-4	NR	Wonli-ATx, HM
Lee [46]	D	1	80	Cervical facet joints	Level of bone surface	Fixed between the joints	1-3	NR	Wonli-ATx
Min [26]	D	0.5	50	Facial atrophic scars	Under the scars	Adhered texture	6	12-24 weeks	NA
Park [41]	D	1.0	50	Wrist ganglion	10	NR	2	36 days	ATx, HM
Park [51]	D	1.0	50	GB12, GB20, GV16 Interspinous ligament of cervical spine Superior angle of scapula	10–20	NR	1-2	NR	ATx, HM
Shin [63]	HC	2.0	50	Tender points of trapezius	Level of muscle	Contractured and tensed texture	1	1	Local anesthesia (lidocaine)
Sung [34]	D	1.0	75	EX-B2 Lumbar facet joint	Level of bone surface	NR	1	1	HM, C
Yoon [40]	D	0.5	50	Subcutaneous fat	Level of subcutaneous fat	Adhered texture	5	10 weeks	Cryotherapy
Yuk [43]	D	1.0	50	**	NR	NR	1-3	NR	ATx, HM, P

Abbreviations: ATx, acupuncture therapy; C, cupping therapy; D, Dongbang acupuncture needle company (Korea); HC, Huaxia acupotome medical equipment factory (China); HK, Hansung precision manufacture (Korea); HM, herbal medicine; N, needle; P, physiotherapy; PATx, pharmacoacupuncture therapy.
†, not listed in the paper, but assumed according to the author's affiliation*, tender point of the mastoid process, interspinous ligament, spinous process, facet joint, and transverse process of the cervical spine; **, teres major, teres minor, latissimus dorsi, trapezius, rhomboid, levator scapula, acromion, humeral head, deltoid, and upper thoracic and lower cervical erector muscles (attachment point).

Table 3
Reports and frequency of adverse events associated with miniscalpel-needle treatment in Korea.

Author (year)	Design	Common AEs	Use of imaging device during the treatment procedure	Number of participants	Number of participants with AEs	Incidence of AEs per 1000 individuals	Number of treatment sessions	Number of treatment sessions resulting in AEs	Incidence of AEs per 1000 treatment sessions
Local AEs									
Jang [31]	CR	Needling pain and discomfort	N	1	1	1000	3	3	1000
Min [26]	CS	Erythema, needling pain	N	4	4	1000	24	24	1000
Park [41]	CR	Needling pain	Y	1	1	1000	2	1	500
Park [51]	CS	Needling pain	Y	2	1	500	3	1	333
Shin [63]	CS	Needling pain and swelling	N	20	5	250	20	5	250
Yoon [40]	CS	Ecchymosis	N	4	NR	NA	20	NR	NA
Yuk [43]	CS	Needling pain	N	5	NR	NA	11	NR	NA
Systemic AEs									
Ko [67]	RS	Headache	Y	73	9†	123	73	9†	123
Lee [37]	RCT	Dizziness, tiredness	N	15	NR	NA	45	NR	NA
No AEs reported									
Jung [49]	CS	NA	Y	3	0	0	3	0	0
Kim [65]	CS	NA	N	7	0	0	12	0	0
Kim [36]	CS	NA	N	5	0	0	15	0	0
Lee [42]	CS	NA	N	47	0	0	78	0	0
Lee [46]	CS	NA	Y	37	0	0	52	0	0
Sung [34]	CCT	NA	N	80	0	0	80	0	0

Abbreviations: AEs, adverse events; CCT, controlled clinical trial; CR, case report; CS, case series; NA, not applicable; NR, not reported; RCT, randomized controlled trial; RS, retrospective survey; SAE, severe adverse event.
* The number of studies reporting the number of patients or treatment sessions with AEs.
† SAEs.
Note: All nine AEs reported in the study by Ko (2010) were SAEsthere were no SAEs in any of the other studies. Lee (2014a), Yoon (2015), and Yuk (2012) did not report the number of participants with AEs. One RCT [Lee (2014a)] was included. Control group interventions in the RCT included acupuncture, herbal medicine, and cupping therapy. One CCT [Sung (2013)] was included. The control group interventions in the CCT included acupuncture, pharmacoacupuncture, and herbal medicine.

but did not specify the frequency (Table 3) [37]. We asked the corresponding author of the study for the missing data, but we failed to receive a reply.

No Grade 4 or 5 AEs were reported. Of the nine studies in which AEs occurred, eight reported the follow-up of AEs, which were reported to resolve within a minimum of 12 h to a maximum of 2 weeks (Table 4).

3.3.3. Safety precautions and infection prevention measures

Safety precautions [25,27,29–39,41–47,49–52,54,56–59,61–63,67–69] and infection prevention measures [25–27,29–39,41–45,47–51,54–56,58,59,62,64–67,69] described in 35 studies each were divided into 10 and 11 subitems, respectively. Subitems under safety precautions included strict assessment before treatment, full anatomical knowledge, sufficient training, use of an imaging device during treatment, entry point marking, and safe MSN technique, while those under infection prevention measures included the use of sterilized medical supplies, disinfection before and after treatment, administration of antibiotics, and provision of education about the dressing and infection prevention after treatment (S1 and S2 Files).

While knowledge of anatomical structures (53.33%), entry point marking before treatment (51.11%), and maintenance of the blade in a parallel orientation to nerves, blood vessels, and muscle fibers (48.89%) were the most common safety precautions, disinfection and sterilization before treatment (71.11%), wearing of surgical gloves (46.67%), and dressing with sterile gauze after treatment (46.67%) were the most common infection prevention measures.

We synthesized these strategies and established the checklist drafts of safety precautions and infection preventions consisting of 10 and 11 sub-items, respectively, to reassess adherence rates in each study (Table 5). As per the results of the reassessed adherence rates, the adherence rate in each study with the following safety precautions was low: pressing of the entry point by the auxiliary hand to fix the target and to separate the nerves and blood vessels during the procedure (8.89%) and checking for pain and numbness during the procedure (13.33%). In addition, adherence with the following infection prevention measures was low: oral antibiotic administration (2.22%) and application of a sterilization wrap (4.44%; Table 5; S3 and S4 Files).

3.4. Quality of AE data reporting

The quality of AEs data in the 15 studies that reported AEs was assessed [26,31,34,36,37,40–43,46,49,51,63,65,67]. The definition of AEs was described in only one study [67]. Nine studies described the methods for AE data collection or monitoring [26,34,36,37,40,46,63,65,67]. The remaining six did not describe the methods [31,41,41,42,43,49,51], although the used methods could be inferred. The frequency and type of AEs associated with MSN treatment were described in all but three studies [26,31,34,36,41,42,46,49,51,63,65,67]. Methods for evaluation of the severity and causality of AEs were described only in three [26,40,42] and two [51,67] studies, respectively. Only one study [34] recorded participants that were lost to follow-up or had withdrawn from the study because of AEs [34] (S5 File).

4. Discussion

The aims of this systematic review were to investigate the characteristics of AEs associated with MSN treatment in Korea and summarize the safety procedural guidelines. This review was conducted as a part of the previously developed protocol to define AEs caused by MSN treatment and to develop safe procedural guidelines considering the clinical settings in Korea [17].

Acupuncture is a treatment modality that induces a recovery reaction through the insertion of needles into the human body. Recently,

Table 4
Clinical response to miniscalpel-needle related adverse events and causality and severity of the adverse events.

Author (year)	Methods used for AE data collection	Coping strategy	Causality	Severity	Practitioner	Author's comment	Follow-up
Jang [31]	(Presumably) Patient reported	Observation	Certain	Grade1	KMD†	On the day after treatment, there was a mild increase in discomfort and pain in the treatment area, although both alleviated within 1 day.	Recovery within 1 day
Jung [49]	(Presumably) Patient/ practitioner reported	NA	NA	NA	Dual license (KMD & WMD)	No AEs were observed.	NA
Kim [65]	Practitioner reported	NA	NA	NA	KMD	No AEs or infection were seen.	NA
Kim [36]	Practitioner reported	NA	NA	NA	KMD	No sign of any AE during the treatment sessions.	NA
Ko [67]	Participant reported	Bed rest, Normal saline (IV), acetaminophen (oral)	Probable	Grade3	KMD†	Headache occurred within 2 days after MSN treatment and lasted for a mean of 6.5 days. It aggravated while sitting and disappeared while lying down; these features are similar to those of headache after lumbar puncture.	Recovery within an average of 6.5 days (range: 1-10)
Lee [37]	Practitioner reported	Observation	Probable /likely	Grade2	KMD	In timid patients, dizziness and a declining response were observed, although these alleviated within 3 days after treatment. There were no hematomas or nerve injuries.	Recovery within 3 days
Lee [42]	(Presumably) Patient/ practitioner reported	Herbal extracts to prevent inflammation*	NA	NA	KMD	No patient suffered from serious or life-threatening complications or loss of physical function after the procedure.	NA
Lee [46]	Practitioner reported	NA	NA	NA	KMD†	There were no AEs.	NA
Min [26]	Practitioner reported	Observation	Certain	Grade1	KMD	There was erythema after the treatment or pain during the treatment, although these were tolerable and mild symptoms that alleviated over time.	Recovery without indication of the period
Park [41]	(Presumably) Patient/ practitioner reported	Herbal medicines with analgesic effect (to prevent pain) Acupuncture at TE5, LI5, and LU8 (to relieve pain)	Certain	Grade1	KMD†	The patient complained of pain at the treatment site the day after treatment.	NR
Park [51]	(Presumably) Patient/ practitioner reported	Observation	Certain	Grade1	KMD†	The pain caused by stimulation of the skin during MSN treatment lasted for about a week. Because the tool itself is thick and flat at the tip, the skin irritation may be caused by the treatment itself, presumably because of excessive histamine release secondary to skin injury or hyperalgesia.	Recovery within 7 days
Shin [63]	(Presumably) Patient/ practitioner reported	Observation	Certain	Grade1	Doctor†	Patients complained of pain and edema at the treatment site for 1 to 3 days, and no other AEs were noted. Both the pain and edema resolved without treatment.	Recovery within 1-3 days
Sung [34]	Practitioner reported	NA	NA	NA	KMD†	No AEs or infection were seen.	No AE
Yoon [40]	Patient reported	Observation	Certain	Grade1	KMD†	No significant AEs occurred during the treatment period. Mild petechiae were observed at the treatment site, although they usually disappeared within 2 weeks.	Recovery within 2 weeks
Yuk [43]	(Presumably) Patient/ practitioner reported	Observation	Certain	Grade1	KMD†	There were no AEs other than a temporary pain increase at the treatment site. The increase in transient pain resolved within 12 hours.	Recovery within 12 hours

Abbreviations: IV, intravenous injection; KMD, Korean Medicine Doctor; MSN, mini-scalpel needle; NA, not applicable (there was no adverse event reported); NR, not reported; Oral, oral administration; WMD, Western medicine doctor.

* Eungyosan (銀翹散) and Baenongsan (排膿散).

† Not listed in the paper, but assumed according to the author's affiliation.

Note: The severity and causality of AEs were assessed by the Common Terminology Criteria for AEs and The World Health Organization-Uppsala Monitoring Centre causality assessment system, respectively.

Table 5
Proposed draft of the guidelines on common safety precautions and infection prevention measures for miniscalpel-needle treatment in Korea.

Category	Safety precautions based on 35 studies on MSN treatment in Korea Subitems	Adherence rate (%)
Practitioner	1) Strict assessment of indications and contraindications	28.89
	2) Full knowledge of anatomical structures	53.33
	3) Sufficient training from experts	17.78
Imaging device	4) Use of an imaging device during the treatment procedure	24.44
	4-1) Ultrasonography	17.14
	4-2) X-ray	8.57
	4-3) C-arm	5.71
Treatment procedure	5) Entry point marking before treatment	51.11
	6) Maintenance of the blade in a parallel orientation to nerves, blood vessels, and muscle fibers	48.89
	7) Pressing of the entry point by the auxiliary hand to fix the target and separate the nerves and blood vessels	8.89
	8) Slow insertion to minimize damage	15.56
	9) Check for pain and numbness during the procedure	13.33
	10) Limited depth of insertion	42.22
	Infection prevention measures based on 35 studies on MSN treatment in Korea	
Category	Subitems	Adherence rate (%)
Medical supplies	1) Sterilized therapeutic tools	36.56
	2) Sterilization wrap	4.44
	3) Surgical mask	33.33
	4) Surgical cap	4.44
	5) Surgical glove	46.67
	6) Operating gown	4.44
Pretreatment	7) Disinfection and sterilization	71.11
	7-1) Povidone iodide or iodine tincture	53.33
	7-2) Alcohol	28.89
	7-3) Boric acid	2.22
	8) Antibiotics	2.22
Post-treatment	9) Disinfection and sterilization	40.00
	10) Dressing with sterile gauze	46.67
	11) Infection prevention education	44.44

MSN: miniscalpel-needle.

acupuncture has been used worldwide and proven to be an effective and cost-effective treatment for musculoskeletal pain [70–72]. As acupuncture is being increasingly and widely used for pain conditions, its safety has also been extensively studied [73]. The incidence of AEs after acupuncture reportedly ranges from 0.14% to 15% [74–79]. In a previous prospective study of AEs associated with acupuncture in 229,230 Germans, the AE rate was 8.6% (19,726 cases) with bleeding and/or hematoma being the most common AE (14,083 cases; 71.4%) followed by pain (4681 cases; 23.7%) [79]. Likewise, research on the safety of acupuncture is actively under way. Moreover, a questionnaire about AEs after acupuncture has been proposed [80], and relevant prospective studies are in progress. MSN is a modern-type of acupuncture tool combining the effects of acupuncture and microinvasive surgery, which has raised some safety related concerns due to its high invasiveness, but can be expected to have a clinically powerful effect especially in musculoskeletal pain. However, the poorly established safety in MSN treatment has limited its availability.

According to our findings, AEs associated with MSN treatment can be classified into mild and local AEs such as needling pain, erythema, or ecchymosis, and moderate-to-severe and systemic AEs such as headache, dizziness, or tiredness. The former symptoms were all reported in case reports or case series, and were determined to have certain causality according to the WHO-UMC causality assessment system and Grade 1 severity according to the CTCAEs scale. Unremarkably, the incidence of AEs varied from 0% [34,36,42,46,49,65] to 100% [26,29,41], which is why we did not perform quantitative synthesis. This high heterogeneity could be attributed to the lack of standardized reporting criteria and safety procedural guidelines for AEs. For example, some studies reported the occurrence of needling pain during the treatment procedure as an AE, while others reported the occurrence of needling pain persistent at 24 h after treatment as an AE. In other words, the incidence of AEs associated with MSN treatment might be influenced by how strict the AE reporting criteria were in a given study. In addition, the safety precautions and infection prevention measures used in each study were heterogeneous, and these procedural differences could also have caused differences in incidence of AEs.

The moderate-to-severe and systemic AEs were reported in one retrospective study and one RCT, and they were assessed to have probable/likely causality according to the WHO-UMC causality assessment system and Grade 2 or 3 severity according to the CTCAEs scale. The retrospective study reported the incidences per 1000 individuals or 1000 treatment sessions of headache after MSN treatment as 123 [67], while the RCT reported dizziness and tiredness occurred in some participants and did not specify the frequency [37]. In particular, headache, which was assessed as a SAE, occurred after MSN treatment for the cervical or lumbar spine, but not after MSN treatment in other areas (Table 4). The authors of that study suggested a similarity with headache after lumbar puncture [67].

In order to prevent AEs associated with MSN treatment, we analyzed the safety precautions [25,27,29–39,41–47,49–52,54,56–59,61–63,67–69] and infection prevention measures [25–27,29–39,41–45,47–51,54–56,58,59,62,64–67,69] in 35 of the 45 included studies (S1 and S2 Files). The most frequently mentioned safety precautions were “full knowledge of anatomical structures” (53.3%), followed by “entry point marking before treatment” (51.1%), “maintenance of the blade in a parallel orientation to nerves, blood vessels, and muscle fibers” (48.9%), and “limited depth of insertion” (42.2%). “Disinfection of the treatment area before the procedure” (71.1%) was the most frequently mentioned infection prevention measure. The most commonly used disinfectant was povidone iodide (53.3%). In addition, more than 40% studies documented “wearing surgical gloves,” “disinfection after treatment,” and “education about infection prevention education” as infection prevention measures. We summarized the drafts of safety precautions and infection prevention measures on the basis of these findings; these can be used as basic data for the development of safety precautions through expert agreement (Table 5).

This study has several strengths. Although MSN treatment is more invasive than acupuncture, there has been no systematic study of the

AEs associated with MSN treatment till date. To our knowledge, this is the first systematic review of AEs associated with MSN treatment. We analyzed the severity, causality, and quality of AE data using the same methodology used in a previous study [19]. In addition, we drafted safety precautions and infection prevention measures on the basis of our analysis. The results of this review can serve as a reference for future studies or policies to enhance the safety of MSN treatment in Korea.

However, some limitations should be noted. Firstly, because the systematic review only included studies conducted in Korea, the results are not representative of AEs associated with MSN treatment worldwide. Secondly, the overall quality of AE data was quite poor. Only 15 of the 45 studies reported AEs associated with MSN treatment. Of these, 12 were case reports or series [26,31,36,40–43,46,49,51,63,65] (Table 3). In addition, only two studies [51,67] evaluated the causality of AEs, while only three [26,40,42] assessed the severity of AEs (Table 1). Because the studies included in this review did not rigorously report AEs, there is a risk of underestimation or overestimation of AEs. In addition, overestimation due to data collected in the case report cannot be ruled out. Therefore, our findings might be controversial. In this systematic review, SAEs such as infection, vascular injury, and nerve damage were not reported. MSN is more invasive than the common filiform needle. Nevertheless, the fact that such SAEs were not reported could have been influenced by the small sample size, poor quality of AE data, and heterogeneity of AE reporting, among other factors. Therefore, we cannot conclude that MSN treatment does not cause SAEs.

Future studies should pay particular attention to the standardization of not only treatment procedures and safety procedures, but also of AE reporting systems. The following should be considered for this: first, need for accurate definition of AEs associated with MSN treatment; second, further clinical studies on MSN treatment to consider a standardized reporting framework that includes exact description of the circumstances, methods, AEs, number of acupoints, insertion site, insertion depth, MSN size, stimulation method, use of medical imaging equipment, clinical experience of the practitioner, patient's condition, AE symptoms, AE resolution, AE duration, and AE causality and severity; and third, an objective and reliable questionnaire for AEs associated with MSN treatment should be established with the utilization of research methodology, such as Delphi research and questionnaire development. A standardized safety guideline is also needed to prevent and reduce the heterogeneity of AEs associated with MSN treatment. Finally, a well-designed study, such as multi-center prospective observational study, evaluating the safety of MSN treatment using the standardized questionnaire, safety registry, or survey for clinicians using MSN treatment, and safety guidelines should be conducted to establish a rigorous evidence of MSN treatment safety.

5. Conclusions

Most of the MSN treatment associated AEs reported were mild symptoms including local pain, while few studies reported moderate-to-severe and systemic AEs such as headache, dizziness, or tiredness. However, due to the high heterogeneity and poor quality of AE data collected, the definite characteristics of the AEs could not be determined. In addition to the types of studies, these differences may have occurred due to differences in the stringency of the AE report and safety procedural guidelines. In order to increase the safety of MSN treatment and reduce the heterogeneity of AE data, we summarized the drafts of safety precautions and infection prevention measures. Our findings could be used to inform and improve the design of future studies, such as multi-center prospective observational studies, safety registry, or survey for clinicians using MSN treatment, to establish the safety of MSN treatment.

Author contributions

All research done by the authors
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Conflicts of interest

The authors declare that there is no conflict of interest regarding the publication of this article.

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Appendix A. Supplementary data

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