Adverse Events

ONLINE TABLE 4

Reference	Reference number	Extracted Text	AEs related to TENS	Statement	Extractable Data	Comment
(Abbasi et al., 2019)	[1]	No statements present	No information to extract	N	N	
(Abelson et al., 1983)	[2]	The only side effect was a slight skin irritation at the site of electrode placement in some of the patients in the transcutaneous electrical nerve stimulation treated group	Skin irritation due to electrodes	Y	N	No numerical data to extract
(Abreu et al., 2010)	[3]	No statements present	No information to extract	N	N	
(Acedo et al., 2015)	[4]	No statements present	No information to extract	N	N	
(Adedoyin et al., 2005)	[5]	No statements present	No information to extract	N	N	
(Ahmed, 2010)	[6]	Due to the absence of complications and adverse effects of TENS compared to conventional opioids and non-opioid analgesics, we suggest that TENS is a safe and reliable therapeutic procedure. – in Discussion	No information to extract	Y – 0 tally	N – 0 tally	Unclear whether the statement on AEs was generic or in relation to the study findings
(Ahmed et al., 2020)	[7]	No statements present	No information to extract	N	N	
(Alcidi et al., 2007)	[8]	No statements present	No information to extract	N	N	
(Ali et al., 1981)	[9]	No statements present	No information to extract	N	N	
(Alizade and Ahmadizad, 2009)	[10]	No statements present	No information to extract	N	N	Only mentions potential irritation of skin in introductory section
(Allais et al., 2003)	[11]	No serious side effects occurred in any group during the study.	Reported no adverse events	Y – 0 tally	N – 0 tally	
(Alm et al., 1979)	[12]	In our group of 75 patients we found no significant skin reactions	No information to extract	N	N	Only relates to skin reaction, not other AEs
(Al-Smadi et al., 2003)	[13]	No statements present	No information to extract	N	N	
(Altay et al., 2010)	[14]	No statements present	No information to extract	N	N	
(Alvarez-Arenal et al., 2002)	[15]	No statements present	No information to extract	N	N	
(Alves Silverio et al., 2015)	[16]	No statements present	No information to extract	N	N	
(Amer-Cuenca et al., 2011)	[17]	No subject reported adverse events such as skin allergy, pain or burning at the electrode site in either active TENS or placebo TENS groups.	Reported no adverse events	Y – 0 tally	N – 0 tally	
(AminiSaman et al., 2020)	[18]	No statements present	No information to extract	N	N	
(Angulo and Colwell Jr, 1990)	[19]	No statement present	No information to extract	N	N	
(Ardic et al., 2002)	[20]	No statements present	No information to extract	N	N	
(Arvidsson and Eriksson, 1986)	[21]	No statements present	No information to extract	N	N	Conclusion states that TENS lacks side-effects.
(Asgari et al., 2018)	[22]	Student's *t*-test and chi-square were applied to compare baseline characteristics and side effects among groups.	No information to extract	N	N	No mention of adverse events in results or discussion despite

Reference	Reference number	Extracted Text	AEs related to TENS	Statement	Extractable Data	Comment
						the method describing how these would be analysed
(Atamaz et al., 2012)	[23]	No statements present	No information to extract	N	N	Flow chart in Fig 1 shows that 6 participants in TENS groups dropped out because of worsening symptoms
(Aydin et al., 2005)	[24]	No complications occurred as a result of the treatments given.	Reported no adverse events	Y – 0 tally	N – 0 tally	
(Azatcam et al., 2017)	[25]	No statements present	No information to extract	N	N	
(Báez-Suárez et al., 2018)	[26]	No patients in any group reported adverse events such as skin allergy or burning at the electrode site.	Reported no adverse events on mothers or new-born babies	Y – 0 tally	N – 0 tally	
(Bai et al., 2017)	[27]	The results of the present study demonstrate that TENS can reduce the intensity of the pain associated with PD without any AEs.	Reported no adverse events	Y – 0 tally	N – 0 tally	
(Baki et al., 2015)	[28]	In our study, TENS has beneficial effects for pain relief after thoracotomy without any side effects; …	Reported no adverse events	Y – 0 tally	N – 0 tally	
(Ballegaard et al., 1985)	[29]	No statements present	No information to extract	N	N	
(Barbarisi et al., 2010)	[30]	No statements present	No information to extract	N	N	In the final visit (visit IX), all the groups underwent a clinical-neurologic examination and routine blood tests to evaluate the possibility of side effects.
(Barker et al., 2006)	[31]	We can recommend this technique because of its simple use and the lack of side-effects in our study population.	Reported no adverse events	Y – 0 tally	N – 0 tally	
(Barker et al., 2008)	[32]	No statements present	No information to extract	N	N	Authors state that patients were asked to report adverse events but these were not recorded in results.
(Başkurt et al., 2006)	[33]	No statements present	No information to extract	N	N	
(Bayindir et al., 1991)	[34]	No statements present Low cost, lack of undesirable side effects, and ease of application can make TENS an acceptable method of reducing postoperative chest pain…..	No information to extract	N	N	No specific mention of monitoring adverse events in methods or results
(Beckwée et al., 2018)	[35]	No statements present …. TENS could be experienced as painful instead of pain relieving, and thus, TENS could have an adverse effect on pain in a subgroup of patients.	No information to extract	N	N	Authors comments refer to patients with central sensitisation
(Benedetti et al., 1997)	[36]	No statements present. We emphasize that the absence of complications and side effects of TENS compared with conventional opioid and nonopioid analgesics makes electrical stimulation a safe and reliable therapeutic procedure.	No information to extract	N	N	

Reference	Reference number	Extracted Text	AEs related to TENS	Statement	Extractable Data	Comment
(Bennett et al., 2010)	[37]	Overall, 9 patients experienced adverse events and median number of adverse events per patient was 2 (range 1, 6). Distribution of adverse events was similar following active or placebo TENS applications (describe in Table 4 of their report)	One adverse event directly related to placebo TENS treatment. Two participants withdrew because of increasing pain.	Y	Y	Authors do not describe nature of adverse events reported in table 4. Data: TENS = 3 events Placebo = 2 events
(Bergeron-Vezina et al., 2018)	[38]	No harms or unintended effects were reported by the participants.	Reported no adverse events	Y – 0 tally	N – 0 tally	
(Bertalanffy et al., 2005)	[39]	No statements present Due to its simplicity and lack of side effects, this method should be considered in these patients.	No information to extract	N	N	
(Bi et al., 2015)	[40]	No statements present	No information to extract	N	N	
(Bilgili et al., 2016)	[41]	No statements present	No information to extract	N	N	
(Binder et al., 2011)	[42]	No statements present	No information to extract	N	N	
(Bjersa and Andersson, 2014)	[43]	No statements present	No information to extract	N	N	
(Bjersa et al., 2015)	[44]	No statements present	No information to extract	N	N	
(Bloodworth et al., 2004)	[45]	No statements present	No information to extract	N	N	
(Bolat et al., 2019)	[46]	"… prevention of unpleasant feelings or complications. A reddish coloration and burning or itching at the electrode–skin junction can occur due to increased blood circulation. However, we observed none of these side effects in the present study".	Reported no adverse events	Y - 0 tally	N	
(Bono et al., 2015)	[47]	Neither adverse events nor side effects occurred in the real or sham group.	Reported no adverse events	Y – 0 tally	N – 0 tally	
(Borjesson et al., 1997)	[48]	No adverse effects were seen……	Reported no adverse events	Y = 0 tally	N = 0 tally	
(Borjesson et al., 1998)	[49]	No statements present	No information to extract	N	N	
(Borup et al., 2009)	[50]	No signs of serious or prolonged side effects were found, neither by using acupuncture nor TENS.	84% of TENS group stated it had no side-effects.	Y = 0 tally	N = 0 tally	No information included on any participants who did experience side-effects.
(Breit and Van der Wall, 2004)	[51]	No statements present	No information to extract	N	N	
(Buchmuller et al., 2012)	[52]	Twelve patients presented a serious adverse event during the study: five in the active TENS group and seven in the sham TENS group. None of these events was considered to be attributable to the treatment studied. Skin irritation was observed in 11 patients in the active TENS group (leading to study discontinuation in one patient) and in three patients in the sham TENS group.	No details about adverse events included in report (except for skin irritation)	Y	Y	Data: TENS = 11 events Placebo = 3 events
(Bulut et al., 2011)	[53]	When side effects were compared, there was no difference between the groups, except skin irritation only in one patient in Group A ($p > 0.05$).	One patient with skin irritation.	Y	N	No numerical data – implies all groups were zero except for

Reference	Reference number	Extracted Text	AEs related to TENS	Statement	Extractable Data	Comment
						Group A but cannot be certain so not extracting
(Bundsen et al., 1982)	[54]	It can thus be concluded that no adverse effect of TNS is demonstrable by clinical, laboratory or neurological examination of the infants after pain relief by TNS	Reported no adverse events	Y = 0 tally	N = 0 TENS ONLY	
(Can et al., 2003)	[55]	No statements present	No information to extract	N	N	
(Casale et al., 2013)	[56]	No statements present	No information to extract	N	N	
(Çebi, 2019)	[57]	No statements present	No information to extract	N	N	
(Celik et al., 2013)	[58]	No side effects of low frequency TENS were seen	Reported no adverse events	Y	Y	No numerical data
(Cetin et al., 2008)	[59]	No statements present	No information to extract	N	N	
(Chandra et al., 2010)	[60]	The incidence of side effects was negligible in both the groups.	Reported no adverse events	Y = 0 tally	N = 0 tally	
(Cheing and Hui-Chan, 1999)	[61]	No statements present	No information to extract	N	N	
(Cheing and Luk, 2005)	[62]	No statements present	No information to extract	N	N	
(Cheing et al., 2002)	[63]	No statements present	No information to extract	N	N	
(Cheing et al., 2003)	[64]	No statements present	No information to extract	N	N	
(Chellappa and Thirupathy, 2020)	[65]	No statements present	No information to extract	N	N	
(Cherian et al., 2016a) – Primary Report Secondary Report (Cherian et al., 2016b)	[66] – Primary Report Secondary Report [67]	Patients were observed for adverse effects due to the TENS device throughout the study. Reports were rare but included local irritation at site of pad placement (n = 2) and irritation due to improper brace fitting (n = 1). All of these were minor and self-limited and did not prevent any patients from continuing a full course of TENS treatment (3 months). There were no serious adverse reactions reported. In addition, patients were evaluated for the need for surgery, either total knee arthroplasty or arthroscopy. From [67] secondary report: Adverse events seen during the trial included skin irritation, increased pain, and local skin breakdown.	Skin irritation – no further information	Y	N	No numerical data from the control group means cannot extract
(Chesterton et al., 2013) Secondary Report (Lewis et al., 2015)	[68] Secondary Report [69]	No adverse reactions to treatment were recorded.	Reported no adverse events	Y = 0 tally	N = 0 tally	
(Chia et al., 1990)	[70]	No statements present	No information to extract	N	N	
(Chiou et al., 2019)	[71]	No statements present	No information to extract	N	N	

Reference	Reference number	Extracted Text	AEs related to TENS	Statement	Extractable Data	Comment
(Chitsaz et al., 2009)	[72]	TENS: Lost to follow-up (n=1) due to difficulties keeping appointments. Nortriptyline: Withdrawal (n=3) due to adverse effects. Nortriptyline was generally well tolerated and most of the adverse events reported were mild in severity. The most common side effects of nortriptyline were dry mouth (n=13), dizziness (n=6), constipation (n=5), urinary retention (n=5), nausea and headache (n=4). In 3 participants, this resulted in early discontinuation of nortriptyline and the dose of nortriptyline could not be increased per protocol due to these side effects. There were no statements about adverse events for TENS present.	Adverse events only in Nortriptyline group.	Y	Y	Data: Use dropout data resulting from AEs TENS = 0 Nortriptyline = 3
(Chiu et al., 2005)	[73]	No complications occurred because of any of the treatments given. The reasons for the withdrawals included insufficient time, dissatisfaction with treatment outcome and worsening of symptoms (Figure 2). 1 withdrawal from TENS group due to worsening of symptoms	Reported no adverse events	Y = 0 tally	N = 0 tally	
(Cipriano et al., 2008)	[74]	Electrical stimulation was well-tolerated by all patients and no relevant side effect was observed.	Reported no adverse events	Y = 0 tally	N = 0 TENS ONLY	
(Cipriano et al., 2014)	[75]	TENS was well tolerated by all patients with no reported side effects.	Reported no adverse events	Y = 0 tally	N = 0 TENS ONLY	
(Coelho de Amorim et al., 2014)	[76]	No statements present	No information to extract	N	N	
(Cooperman et al., 1977)	[77]	No statements present	No information to extract	N	N	
(Coyne et al., 1995)	[78]	No statements present	No information to extract	N	N	
(Crompton et al., 1992)	[79]	However, a substantial proportion of women who used the device found it frightening or unpleasant, which we consider unacceptable in the absence of an improvement in pain scores.	Participants found the TENS device 'frightening' and 'unpleasant'.	Y	N	No numerical data
(Cuschieri et al., 1985)	[80]	All patients tolerated the TES device well.	Reported no adverse events	Y = 0 tally	N = 0 TENS ONLY	
(Cuschieri et al., 1987)	[81]	No untoward side effects were noted.	Reported no adverse events	Y = 0 tally	N = 0 tally	
(da Silva et al., 2008)	[82]	No statements present	No information to extract	N	N	
(da Silva et al., 2015)	[83]	No adverse effects were observed in the TENS group, but 33.3 % of patients in the control group reported drowsiness and nausea.	Reported no adverse events in TENS group	Y	Y	The authors reported stated that 'adverse events for TENS' was an outcome and they presented this data as AEs attributable to the interventions per se. For this reason, we have extracted the data. Nevertheless, we are

Reference	Reference number	Extracted Text	AEs related to TENS	Statement	Extractable Data	Comment
						concerned that this data reflects efficacy of interventions to reduce AEs (drowsiness, nausea,) associated with drugs (morphine, Dipyrone) rather than TENS Data: TENS = 0 events / 21 Control = 7 events / 21 participants
(Dailey et al., 2013)	[84]	No statements present	No information to extract	N	N	
(Dailey et al., 2020)	[85]	There were 30 adverse events related to TENS intervention in 30 participants on visits 1, 2, or 3. The most common adverse events were pain with TENS (4.8% in the active TENS group, 4% in the placebo TENS group, and 1% in the no TENS group) and skin irritation with electrodes (4.8% in the active TENS group, 1% in the placebo TENS group, and 0% in the no TENS group). Adverse events reported on visit 2 occurred during the first treatment at that visit, and adverse events reported on visit 3 were during treatment at that visit and during the 4-week period of home use. Serious Adverse Events. In the course of the trial, four serious adverse events (study related, n=1 and non-study related, n=3) were reported between April 2014 and April 2016 and all were categorized as hospitalization. For the study related event, the participant complained of chest pain during the 6MWT, was admitted to ER, hospitalized without diagnosed myocardial damage and recovered with treatment. For the three participant's categorized as non-study related: (1) report of chest pain at home, referred to primary care provider, admitted to ER and hospitalized with changes for thyroid medication and recovered with treatment (2) report of GI symptoms, admitted to hospital for dehydration and recovered with treatment and (3) report of depression, admitted to hospital for treatment and condition was still present and being treated at the end of her participation in the study. As a group, for these four participants, the average age was 49.75 years, ranging from 40 to 59 years. With respect to treatment group, one event occurred prior to randomization and three occurred after randomization to treatment groups (placebo-TENS, n=1 and no-TENS, n=2). The participants were further	Y	Y	Y	TENS = 17/103 Placebo = 3/119 Taken from data in Supplementary Table 7, available on the Arthritis & Rheumatology web site at http://onlin elibrary.wiley.com/doi/10.1002/art.41170/ abstract, shows rates of TENS-related Adverse events by visit. There were 4 serious adverse events, with none related to TENS use (Supplementary Results, http://onlin e library.wiley.com/doi/10.1002/art.41170/ abstract).

Reference	Reference number	Extracted Text	AEs related to TENS	Statement	Extractable Data	Comment
		categorized by medication (opioid, n=1 and non-opioid, n=3) and location (TN, n=3 and IA, n=1).				
(Davies, 1982)	[86]	No statements present	No information to extract	N	N	
(Dawood and Ramos, 1990)	[87]	Four subjects noticed muscle vibrations, change in stimulation with movements, tightness, headaches after use, and a slight redness or a burning sensation with TENS treatment. No mention of AEs in the Ibuprofen group	Reported no adverse events	Y	N = 0 TENS ONLY	No numerical data for the comparison groups (placebo, ibuprofen)
(De Angelis et al., 2003)	[88]	No differences in side effects were observed between TENS versus no TENS groups. … the incidence of nausea was quite high in this patient sample as compared with other studies (group TENS, 8.5%; group No TENS, 11.3%) (11, 12), but this symptom was mentioned by the patient only when specifically elicited and it was probably the result of psychosomatic factors or emotional stress. However, shoulder pain was more frequent, albeit not significantly, in group TENS than in group Control (group A, 3%; group B, 0%). This is probably due to the fact that the examination lasted longer in group A than in group B (group A, 134.1 60 seconds; group B, 117 49 seconds; P .054) (using the same CO2 flow) and that the patients' acceptance of the procedure was higher with the use of the TENS device. It is completely safe, noninvasive, and free from any side effects … as far as side effects are concerned, there were no statistically significant differences in favor of the TENS device…..	Coded as: Reported no adverse events Extract data AEs = Nausea and Shoulder pain but not attributed to pain	Y = 0 tally	N = 0 tally	No data extracted It is difficult to ascertain whether these symptoms were AEs or due to treatment intervention of surgical procedure No data extracted
(De Giorgi et al., 2017)	[89]	No side effects were referred by the patients during the 10-week TENS treatment.	Reported no adverse events	Y = 0 tally	N = 0 TENS ONLY	
(de Oliveira, 2012)	[90]	No statements present	No information to extract	N	N	
(de Orange et al., 2003)	[91]	No statements present	No information to extract	N	N	
(de Sousa et al., 2014)	[92]	No statements present	No information to extract	N	N	
(DeSantana et al., 2008)	[93]	We reinforce that the absence of complications and adverse effects of TENS compared with conventional opioids and nonopioid analgesics makes TENS a safe and reliable therapeutic procedure.	Reported no adverse events	Y = 0 tally	N = 0 TENS ONLY	
(DeSantana et al., 2009)	[94]	We conclude that the absence of complications and adverse effects of TENS compared with conventional opioids and nonopioid analgesics makes TENS a safe and reliable therapeutic procedure.	Reported no adverse events	Y = 0 tally	N = 0 TENS ONLY	
(Dewan and Sharma, 2011)	[95]	No statements present	No information to extract	N	N	
Deyo et al. (1990)	Deyo, Walsh [96]	Approximately one-third of the subjects reported minor skin irritation at the sites of electrode placement, with equal proportions in the true-TENS and sham-TENS groups.	Skin irritation. One subject had to discontinue due to severe dermatitis.	Y	N	No numerical data
(Dibenedetto et al., 1993)	[97]	Both treatments were well-tolerated and no side-effects reported.	Reported no adverse events	Y = 0 tally	N = 0 tally	

Reference	Reference number	Extracted Text	AEs related to TENS	Statement	Extractable Data	Comment
(Dilekci et al., 2016)	[98]	No statements present	No information to extract	N		
(Dissanayaka et al., 2016)	[99]	No statements present	No information to extract	N	N	
(Dogu et al., 2008)	[100]	No statements present	No information to extract	N	N	
(Domaille and Reeves, 1997)	[101]	No statements present	No information to extract	N	N	
(Ebadi et al., 2018)	[102]	As for side effects, 8 patients in the Diadynamic group reported a burning sensation in the first 3-4 min of the treatment.	Reported no adverse events in TENS group.	Y	N	No numerical data for TENS
(Ekblom and Hansson, 1987)	[103]	No statements present	No information to extract	N	N	
(Ekim et al., 2008)	[104]	No statements present	No information to extract	N	N	
(Elboim-Gabyzon et al., 2019)	[105]	No statements present	No information to extract	N	N	
(Elserty et al., 2016)	[106]	No statements present	No information to extract	N	N	
(Emmiler et al., 2008)	[107]	Post-op complications (atelectesia) were tabulated but not stated whether these were attributed to the intervention TENS = 1/20(5%) Placebo = 1/20(5%) Control = 4/20 (20%)	Reported adverse events (complication) atelectesis	Y	N	No data extracted – unclear whether 'complications' attributable to the treatment
(Engen et al., 2016)	[108]	No statements present	No information to extract	N	N	
(Erden and Senol Celik, 2015)	[109]	No statements present	No information to extract	N	N	
(Erdogan et al., 2005)	[110]	We did not observe any side effects using TENS, although we did not use TENS in patients who had cardiac disease.	Reported no adverse events	Y = 0 tally	N = 0 TENS ONLY	
(Erkkola et al., 1980)	[111]	No statements present	No information to extract	N	N	
(Escortell-Mayor et al., 2011) Secondary Report (Escortell Mayor et al., 2008)	[112] Secondary Report [113]	It is remarkable, as it is described in a publication done by this group, that no important adverse effects were observed from either therapy - Reported no adverse events [112]p70 Translated from [113] p340 16.3% of treated patients with TENS (n = 7) and 6.4% of those treated with manual therapy (n = 3) reported adverse effects related to treatment. Three of them presented increased pain in the treated area and 1, general poor physical condition in the group treated with TENS Of those who received therapy manual, 1 patient referred a clinical worsening the first days and the rest did not detail symptoms.	Information to extract	Y	Y	Data extracted from secondary report [113]: TENS = 7 events Manual Therapy = 3 The statement on AEs in [112]p70 appears to contradict data presented in [113]
(Esteban Gonzalez et al., 2015)	[114]	There were no complications, intolerances or other problems that required the intervention with TENS to be suspended in any of the 50 patients.	Reported no adverse events	Y = 0 tally	N = 0 TENS ONLY	
(Eyigor et al., 2008)	[115]	No statements present	No information to extract	N	N	

Reference	Reference number	Extracted Text	AEs related to TENS	Statement	Extractable Data	Comment
(Eyigor et al., 2010)	[116]	No significant adverse event was reported in either of the two groups (p>0.05).	Reported no adverse events	Y = 0 tally	N = 0 tally	
(Facci et al., 2011)	[117]	No statements present	No information to extract	N	N	
(Farahani et al., 2014)	[118]	No statements present	No information to extract	N	N	
(Farina et al., 2004)	[119]	No statements present	No information to extract	N	N	
(Fatima and Sarfraz, 2019)	[120]	No statements present	No information to extract	N	N	
(Ferraz and Moreira, 2009)	[121]	No statements present	No information to extract	N	N	
(Ferreira et al., 2011)	[122]	No statements present	No information to extract	N	N	
(Ferreira et al., 2017)	[123]	No statements present	No information to extract	N	N	Dropouts reported but reasons not given
(Finsen et al., 1988)	[124]	No statements present	No information to extract	N	N	
(Fiorelli et al., 2012)	[125]	We did not observe any side effects; thus, TENS may be particularly useful for patients that have liver or kidney disease……	Reported no adverse events	Y = 0 tally	N = 0 tally	
(Fodor-Sertl et al., 1990)	[126]	No statements present	No information to extract	N	N	
(Forogh et al., 2019)	[127]	No adverse events occurred and the rate of compliance to the exercise program was high in both groups	Reported no adverse events	Y = 0 tally	N = 0 tally	
(Forst et al., 2004)	[128]	No statements present	No information to extract	N	N	
(Forster et al., 1994)	[129]	No statements present	No information to extract	N	N	
(Fujii-Abe et al., 2019)	[130]	None of the study patients suffered any abnormal or harmful effects.	Reported no adverse events	Y = 0 tally	N	
(Galli et al., 2015)	[131]	No statements present	No information to extract	N	N	
(Galloway et al., 1984)	[132]	Only one of our patients demonstrated any adverse effects of the treatment in the form of an allergic rash with blistering which, in patter, was seen to correspond exactly with the areas of contact with the adhesive incorporated in the sterile wound electrodes.	Allergic skin irritation in one participant	Y	N	No numerical data
(Garcia-Perez et al., 2018)	[133]	No statements present	No information to extract	N	N	
(Gerson et al., 1977)	[134]	No statements present	No information to extract	N	N	
(Ghoname et al., 1999a)	[135]	No statements present	No information to extract	N	N	
(Ghoname et al., 1999b)	[136]	No statements present	No information to extract	N	N	
(Gilbert et al., 1986)	[137]	No statements present	No information to extract	N	N	
(Grabiańska et al., 2015)	[138]	No statements present	No information to extract	N	N	
(Graff-Radford et al., 1989)	[139]	No statements present	No information to extract	N	N	Patients were informed about possible side-effects beforehand
(Grant et al., 1999)	[140]	……three TENS patients developed skin reactions. Other than these, reported side effects were minimal: three acupuncture patients reported dizziness and three TENS patients developed skin reactions.	Skin reactions in 3 participants	Y	Y	Data extracted: TENS = 3 events Acupuncture = 3 events
(Gregorini et al., 2010)	[141]	No statements present	No information to extract	N	N	
(Grimmer, 1992)	[142]	No statements present	No information to extract	N	N	
(Gschiel et al., 2010)	[143]	Overall, there were no side effects.	Inferred no adverse events	Y	N = 0 tally	No numerical data

Reference	Reference number	Extracted Text	AEs related to TENS	Statement	Extractable Data	Comment
(Gunay Ucurum et al., 2018)	[144]	No statements present	No information to extract	N	N	
(Guo and Jia, 2005)	[145]	No statements present	No information to extract	N	N	
(Hamza et al., 1999)	[146]	….16 -20% of the patients in each of the four groups complained that the TENS adversely influenced their quality of sleep because of the presence of the cutaneous electrodes and wires.	Sleep interference because of electrodes/wires.	Y	N	No numerical data for other groups
(Hanfy and El-Bigawy, 2004)	[147]	No statements present During the study TENS therapy was safe and allowed the patients to remain ambulatory.	No information to extract	N	N	No specific comments on adverse events included
(Hansson and Ekblom, 1983)	[148]	…. it should be noted that most patients found the muscle twitches produced by the low frequency TENS uncomfortable.	No information to extract	N	N	No specific comments on adverse events included
(Hansson et al., 1986)	[149]	No statements present	No information to extract	N	N	
(Hargreaves and Lander, 1989)	[150]	No statements present	No information to extract	N	N	Authors state that TENS is safe but no specific comments on side-effects in this study
(Harrison et al., 1986)	[151]	In the present study, like all others reported to-date, no side-effects were noted from the therapy.	Reported no adverse events	Y	N = 0 tally	No numerical data
(Hart et al., 2012)	[152]	No statements present	No information to extract	N	N	
(Hazneci et al., 2005)	[153]	No statements present	No information to extract	N	N	
(Herrera-Lasso et al., 1993)	[154]	No statements present	No information to extract	N	N	
(Hershman M, 1989)	[155]	No statements present	No information to extract	N	N	
(Hou et al., 2002)	[156]	No statements present	No information to extract	N	N	
(Hokenek et al., 2020)	[157]	No treatment-related skin reactions or unwanted effects were encountered during the trial. Of the verum group, 3 patients declined continuation of treatment due to intolerance to paresthesia, and 2 patients in the sham group declined to continue treatment due to intolerable pain. These patients opted to instead receive 0.75 mg/kg meperidine rescue therapy and were excluded from the trial.	Unclear whether these are adverse events or dislike of TENS sensation and worsening pain due to non response to sham	Y	N	
(Hruby et al., 2006)	[158]	No statements present	No information to extract	N	N	
(Hsieh et al., 1992)	[159]	No statements present … One-shot TENS treatment may be recommended due to the rarity of side effects and its convenient application.	No information to extract	N	N	
(Hsueh et al., 1997)	[160]	No statements present	No information to extract	N	N	
(Hughes et al., 1988)	[161]	The use of TENS had no adverse effects upon the newborn	Reported no adverse events	Y	N = 0 TENS ONLY	No numerical data
(Husch et al., 2020)	[162]	No statements present	No information to extract	N	N	
(Ilhanli, 2015)	[163]	There were no adverse events due to treatment regimens.	Reported no adverse events	Y	N = 0	
(Inal et al., 2016)	[164]	No statements present	No information to extract	N	N	

Reference	Reference number	Extracted Text	AEs related to TENS	Statement	Extractable Data	Comment
(Isik et al., 2017)	[165]	There were no serious side effects in both groups. In the TENS group no side effects were reported although 21 of the patients reported the treatment as boring due to the long hospital stay. In the leech therapy group, there was a mild local itching and skin redness in 31patients (12 patients required topical antihistamine therapy) and severe local itching and reddening in 3 patients (requiring oral plus topical antihistamine therapy).	Reported no adverse events	Y	Y	TENS = 0 events / 53 participants Leech = 34 events / 52 participants
(Jaafarpour et al., 2008)	[166]	No statements present	No information to extract	N	N	
(Jamison et al., 2019)	[167]	None of the participants reported experiencing any long-term adverse effects from using the hfTENS.	Reported no adverse events	Y	N = 0 TENS ONLY	No numerical data
(Jarzem et al., 2005)	[168]	No statements present	No information to extract	N	N	
(Jensen et al., 1985)	[169]	No statements present	No information to extract	N	N	
(Jensen et al., 1991)	[170]	No statements present	No information to extract	N	N	
(Jones and Hutchinson, 1991)	[171]	Three patients complained of dizziness after Entonox inhalation. There were no other side-effects of any of the treatments. TENS produced no side-effects, is easier to handle and was subjectively preferred by the patients.	Reported no adverse events	Y	N = 0	No data extracted Multiple cross over study with possibility of contamination between treatments
(Kara et al., 2011)	[172]	Furthermore, there were no adverse effects or negative results related to TENS application.	Reported no adverse events	Y	N = 0 TENS ONLY	No numerical data
(Kararmaz et al., 2004)	[173]	TENS is a non-invasive, safe, and simple treatment method, which does not have any systemic side effects. We did not observe any difficulties in the use of TENS. NOTE: Table 4 records side effects associated with ESWL procedure as an efficacy measure	Reported no adverse events	Y	N = 0 TENS ONLY	No numerical data associated with AEs due to treatment interventions under study The only side-effects reported were medication-induced
(Kayman-Kose et al., 2014)	[174]	No adverse effects due to TENS occurred during the study period - for both Cesarean and vaginal delivery data	Reported no adverse events	Y	N = 0 TENS ONLY	No numerical data
(Keskin et al., 2012)	[175]	No adverse effect of TENS application on pregnant women was observed during the study.	Reported no adverse events	Y	N	No numerical data for comparison group
(Kibar et al., 2020)	[176]	No statements present	No information to extract	N	N	
(Kim et al., 2012)	[177]	There were no significant differences in the incidences of side effects such as erythema and itching between the groups ($P > 0.05$). TENS Group 7/50 (14%) had erythema and 1/50 (2%) had itching. Table II of their report	Erythema and itching.	Y	Y	Data extracted: TENS = 8 events / 50 participants Placebo = 7 / 50 participants
(Kim et al., 2014)	[178]	No major adverse effects were reported by participants in any treatment group. One patient in the monotherapy group, one patient in the TENS+Np group, and one patient in the CAP+Np group experienced skin itching. One patient in the TENS+Np group and one patient in the HEAT+Np group	Itching and sleep disturbance	Y	Y	Data extracted (skin itching): TENS + NSAID patch = 1 event / 24 participants

Reference	Reference number	Extracted Text	AEs related to TENS	Statement	Extractable Data	Comment
		reported sleep disturbance. Light somnolence was reported by one patient in the monotherapy group. However, all adverse effects had spontaneously resolved by the end of this study without any treatment. Participants' vital signs were in the normal				NSAID patch alone = 1 event / 25 participants
(Kirupa et al., 2019)	179	No statements present	No information to extract	N	N	
(Knobel et al., 2005)	180	In this survey, more than 50% of women reported some discomfort in the use of electrodes type SSP and 25% in the use of electrodes plate type (Tab. 4). In the application of stimulation, no woman reported discomfort in none of the study groups. To assess the effectiveness of this care, therefore, research is needed to reveal the woman's opinion about the method	Discomfort during stimulation	Y	N	No data extracted Discomfort was an outcome measure – comparing two TENS electrodes. We did not consider discomfort as an adverse event in this study
(Koca et al., 2014)	181	No serious complication was associated with the treatments in any group, and all patients generally tolerated the treatments well. Only two patients in the TENS group experienced mild tenderness at the application site.	Mild tenderness	Y	N	No numerical data
(Kofotolis et al., 2008)	182	No statements present	No information to extract		N	
(Koke et al., 2004)	183	During the first period, skin irritation occurred in 9.4% (17/180) of all patients, adherence problems of electrodes in 12.2% (22/180) and problems attaching electrodes in 2.2% (4/180). In four patients, the adverse effects resulted in withdrawal from the study (skin-irritation 2X, problems attaching electrodes 2 X). During the second period, skin irritation was reported by 5.8% (10/171), adherence problems of electrodes 4.7% (8/171), and problems attaching electrodes body 2.9% (5/171). No significant differences in adverse effects were found between groups. At 6 months follow-up, 6 patients (3 in HFT–COT group and 3 in HIT–COT group) reported skin irritation due to TENS, but still could use TENS regularly.	Skin irritation Problems attaching electrodes	Y	N	Could not extract data at 6 months follow-up (skin irritation) because could not ascertain the number of participants remaining in each group High frequency TENS = 3 events High intensity = 3 Cross-over study whereby all participants received an active TENS for all possible interventions
(Korkmaz et al., 2010)	184	No serious side-effects or complications were observed in either of the two groups (P>0.05).	Reported no adverse events	Y = 0 tally	N = 0 tally	No numerical data
(Kumar and Raje, 2014)	185	No statements present	No information to extract	N	N	
(Labrecque et al., 1999)	186	No statements present	No information to extract	N	N	
(Laitinen and Nuutinen, 1991)	187	No statements present	No information to extract	N	N	
(Lang et al., 2007)	188	Because of its simple use and lack of side effects in our study population, we can recommend this technique for pain therapy.	Reported no adverse events	Y	N = 0 TENS ONLY	No numerical data

Reference	Reference number	Extracted Text	AEs related to TENS	Statement	Extractable Data	Comment
(Langley et al., 1984)	[189]	No adverse side-effects were reported by patients receiving TNS or placebo.	Reported no adverse events	Y = 0 tally	N = 0 tally	
(Lauretti et al., 2013)	[190]	Concerning adverse effects, 2 patients from the STG got in sleep after the device application and complained of muscle sore due to more than 70-min active device application, which was subsequently improved by local hot application.	Muscle soreness in TENS group (2 patients)	Y	N	Note: the poor English in the quotation is how the text was written!
(Lauretti et al., 2015)	[191]	In conclusion, the portable TENS device demonstrated to be efficacious for pain relief and improvement of quality of life with no adverse effects for control of menstruation cramp pain.	Reported no adverse events	Y	N = 0 TENS ONLY	
(Law and Cheing, 2004)	[192]	No statements present	No information to extract	N	N	
(Law et al., 2004)	[193]	No statements present	No information to extract	N	N	
(Leandri et al., 1990)	[194]	No statements present	No information to extract	N	N	
(Lee et al., 1990)	[195]	No negative effects on the mothers and babies were reported.	Reported no adverse events	Y = 0 tally	N = 0 tally	
(Lee et al., 2015)	[196]	Neither expected nor unexpected AEs occurred in the study and control groups.	Reported no adverse events	Y = 0 tally	N = 0 tally	
(Lee et al., 2019)	[197]	No statements present	No information to extract	N	N	
(Leo et al., 1986)	[198]	No statements present	No information to extract	N	N	
(Leonard et al., 2011)	[199]	No statements present	No information to extract	N	N	
(Lewers et al., 1989)	[200]	No statements present	No information to extract	N	N	
(Lewis et al., 1984)	[201]	No statements present	No information to extract	N	N	One patient dropped out because of worsening pain.
(Lewis et al., 1994)	[202]	No statements present	No information to extract	N	N	
(Likar et al., 2001)	[203]	The side effects 1 patient in the Verum group about vomiting, 5 patients in the placebo group suffered from nausea and vomiting that are considered easy and were classified as medium. TENS + analgesics = 1 event / 11 participants Placebo TENS + analgesics = 5 event / 12 participants		Y	N	Data related to nausea and vomiting. Debatably this is related to AE associated with post op drugs rather than TENS. We decided not to extract this data because nausea and vomiting AE of drugs reflects efficacy of TENS rather than AE of TENS
(Lim et al., 1983)	[204]	No statements present	No information to extract	N	N	
(Lima et al., 2011)	[205]	No statements present	No information to extract	N	N	
(Limoges and Rickabaugh, 2004)	[206]	In addition, no adverse events secondary to TENS use or procedural complications occurred.	Reported no adverse events	Y	N = 0 TENS ONLY	No numerical data
(Lin et al., 2015)	[207]	No statements present	No information to extract	N	N	
(Lin et al., 2019)	[208]	First, there were no adverse events (such as discomfort, hematoma, injury, or hyperalgia) throughout this study.	Reported no adverse events	Y = 0 tally	N = 0 tally	

Reference	Reference number	Extracted Text	AEs related to TENS	Statement	Extractable Data	Comment
(Linde et al., 1995)	[209]	The most common side effect during TENS treatment is some type of hypersensibility reaction of the skin. It was mostly seen in slightly underweight patients, in whom contact between skin and electrode was not at its maximum, especially in the area of the TMJ	Skin reaction (no other details)	Y	N	No numerical data
(Linn et al., 1999)	[210]	No statements present	No information to extract	N	N	
(Lison et al., 2017)	[211]	No patients in either the active or placebo TENS groups reported adverse events such as skin allergy, pain, or burning at the electrode site.	Reported no adverse events	Y = 0 tally	N = 0 tally	
(Liu et al., 1985)	[212]	No statements present	No information to extract		N	
(Liu et al., 2017)	[213]	During treatment, only 1 patient in the 2-Hz tONS group reported an adverse event. This was intolerance to a form of pinch pain induced by electrical stimulation. However, when the intensity of stimulation was reduced from 10 to 9 mA, the uncomfortable feeling subsided. In the TPM group, 9 of 22 patients experienced (mostly mild) paresthesia, especially of the hands and feet. No other adverse events were reported. tONS = transcutaneous occipital nerve stimulation	Pain at 10mA. Pain lessened when intensity reduced.	Y	Y	Data extracted TENS = 1 event / 22 - Pinch pain Topiramate = 9 / 22 - Mild paraesthesia of hands
(Lofgren and Norrbrink, 2009)	[214]	In this study few side-effects were reported. Three patients reported increased pain, 2 after TENS and one after warmth.	Increased pain in 2 patients	Y	Y	Data extracted (increased pain) TENS = 2 events / 32 participants Warmth therapy = 1 event / 32 32 participants
(Luchesa et al., 2009)	[215]	No statements present	No information to extract	N	N	
(Lundeberg, 1984)	[216]	No statements present	No information to extract	N	N	
(Lundeberg et al., 1985)	[217]	No statements present	No information to extract	N	N	
(Machado et al., 2019)	[218]	No statements present	No information to extract	N	N	
(Machin et al., 1988)	[219]	No statements present	No information to extract	N	N	
(Mahure et al., 2017)	[220]	No TENS machine-related complication, such as localized pain or erythema at the electrode site, occurred in either group of patients.	Reported no adverse events	Y	N = 0 Tally	No numerical data despite clear statement of no events in both groups
(Manigandan et al., 2014)	[221]	No statements present	No information to extract	N	N	
(Mannheimer and Carlsson, 1979)	[222]	No side effects were observed.	Reported no adverse events	Y = 0 tally	N = 0 tally	
(Mannheimer and Whalen, 1985)	[223]	No statements present	No information to extract	N	N	
(Mannheimer et al., 1978)	[224]	No side effects of the treatment were observed. One patient reported that when the pain recurred it was more severe than before TNS, however.	Pain recurred more severe than before TNS	Y	N	
(Mannheimer et al., 1985)	[225]	One patient in the treatment group was excluded because of skin irritation from the electrodes….	Skin irritation	Y	N	
(Mansourian et al., 2019)	[226]	No statements present	No information to extract	N	N	
(Mansuri et al., 2019)	[227]	No statements present	No information to extract	N	N	
(Mansuri et al., 2020)	[228]	No statements present	No information to extract	N	N	
(Marchand et al., 1993)	[229]	No statements present	No information to extract	N	N	

Reference	Reference number	Extracted Text	AEs related to TENS	Statement	Extractable Data	Comment
(Mascarin et al., 2012)	230	No statements present	No information to extract	N	N	
(McCallum et al., 1988)	231	No statements present	No information to extract	N	N	
(Melzack et al., 1983)	232	No statements present	No information to extract	N	N	
(Merrill, 1989)	233	No statements present	No information to extract	N	N	
(Miller et al., 2007)	234	No statements present	No information to extract	N	N	
(Milsom et al., 1994)	235	Ten of the 12 women considered the high-intensity transcutaneous nerve stimulation to be painful. However, stimulation lasted only a few seconds, and all the women were prepared to accept again this short period of pain to obtain pain relief from dysmenorrhea.	Painful at high-intensity stimulation	Y	N	
(Moharic et al., 2009)	236	As already indicated in the Methods section, three patients in the pregabalin group experienced such severe somnolence and dizziness that they had to withdraw from the study. Complaints in the combined group beside somnolence and dizziness included peripheral oedema, weight gain, elevated blood glucose values and withdrawal headache, while one patient from the combined group withdrew from the study because of a traffic accident (tractor overturning) caused by somnolence induced (with all likelihood) by pregabalin. In the TENS group, none of the patients reported any local or systemic side effects, neither did they report any problems with continuous TENS application for three hours daily.	Reported no adverse events	Y	Y	Data extracted (severe somnolence and dizziness) TENS = 0 events / 46 participants Pregabalin alone = 3 events / 8 participants resulting in study withdrawal
(Mondal et al., 2019)	237	No statements present	No information to extract	N	N	
(Moore and Shurman, 1997)	238	No adverse treatment effects were reported and no subject reported the addition of any new pain medication, physical therapy, or other pain-related treatment during the course of their study participation.	Reported no adverse events	Y = 0 tally	N = 0 tally	
(Mora et al., 2006)	239	We can recommend this technique due to its simple use and the lack of side effects in our study population.	Reported no adverse events	Y = 0 tally	N = 0 TENS ONLY	
(Morgan et al., 1996)	240	No statements present	No information to extract	N	N	
(Møystad et al., 1990)	241	No statements present. TNS may have advantages as a non-invasive method with few side effects that is simple to administer for the patients themselves.	No information to extract	N	N	
(Murray et al., 2004)	242	No statements present	No information to extract	N	N	
(Mutlu et al., 2013)	243	No statements present	No information to extract	N	N	There were dropouts to follow-up but no explanation for these.
(Nabi et al., 2015)	244	The therapeutic methods studied here were well tolerated were not associated with any serious adverse effects. However, skin irritation was reported in a few TENS group subjects.	Skin irritation	Y	N	No numerical data
(Nash et al., 1990)	245	The only side effected noted in the series were occasional skin rashes due to allergy to the electrode jelly or fixing tape, and occasional patients had transient increase in pain which settled to previous levels with cessation of treatment.	Skin irritation Transient increase in pain	Y	N	No numerical data

Reference	Reference number	Extracted Text	AEs related to TENS	Statement	Extractable Data	Comment
(Navarathnam et al., 1984)	[246]	Some of the patients in both groups developed blisters around the electrode edges in the distribution of the adhesives. In addition, two patients developed small areas of pressure necrosis in the region of the lumbosacral electrodes which might be avoided by more attention to posture of the patients with these electrodes.	Skin irritation Lumbosacral pressure necrosis	Y	N	No numerical data
(Neary, 1981)	[247]	No cases of infection or skin reaction were observed. TENS did not mask the pain symptoms from complications.	Reported no adverse events	Y = 0 tally	N = 0 tally	
(Neighbours et al., 1987)	[248]	No statements present	No information to extract	N	N	
(Nesheim, 1981)	[249]	No statements present	No information to extract	N	N	
(Neumark et al., 1978)	[250]	No statements present	No information to extract	N	N	
(Ng et al., 2003)	[251]	No statements present	No information to extract	N	N	
(Nordemar and Thorner, 1981)	[252]	No statements present	No information to extract	N	N	
(Norrbrink, 2009)	[253]	Three patients experienced discomfort or increased pain during treatment, and one patient experienced local muscle spasms.	Increased pain during treatment Local muscle spasms	Y	N	No numerical data Unclear which group experienced side effects
(Olsén et al., 2007)	[254]	No adverse effects except for discomfort during stimulation were recorded. Discomfort from the stimulation itself was greater in the HI TENS group than in the LI TENS group (pB/0.01). In the HI TENS group, two women experienced severe discomfort, two women experienced moderate discomfort, five women experienced mild discomfort, and two women experienced no discomfort. Seven women in the LI TENS group experienced no discomfort and one woman experienced mild discomfort from the stimulation given. No adverse effects except for discomfort during stimulation were recorded.	Discomfort during stimulation	Y	N	No numerical data other than stimulation discomfort Decided not to extract this
(Fagevik Olsen et al., 2019)	[255]	No statements present	No information to extract	N	N	Dropouts recorded but reasons not given
(Oncel et al., 2002)	[256]	No complications due to TENS therapy or Naproxen sodium were seen during the study.	Reported no adverse events	Y = 0 tally	N = 0 tally	
(Oosterhof et al., 2006) Secondary reports (Oosterhof et al., 2008, Oosterhof et al., 2012a, Oosterhof et al., 2012b)	[257] Secondary reports [258-260]	No statements present in [257]. No statements present in secondary report [259] Secondary report - [260] Skin irritation occurred at some time point in half of the patients but could easily be cured by changing the type of electrode, except for 4 patients who had to stop treatment. Because there was no difference between TENS and sham TENS, we assume there was no interaction of the electric current with electrode material, which has been suggested.	Skin irritation	Y	N	No numerical data
(Ordog, 1987)	[261]	No complications of treatment were found. No side effects were reported, except a mild tingling sensation at higher TENS-PAC® output levels.	Reported no adverse events Mild tingling sensation is part of the TENS treatment	Y = 0 tally	N = 0 TENS ONLY	

Reference	Reference number	Extracted Text	AEs related to TENS	Statement	Extractable Data	Comment
		Overall, 20% of the patients reported this effect, but none had to discontinue usage of the TENS-PAC® because of it.				
(Ozkaraoglu et al., 2020)	[262]	No statements present	No information to extract	N	N	
(Ozkul et al., 2015)	[263]	No unwanted effects occurred during the application of both treatments.	Reported no adverse events	Y = 0 tally	N = 0 tally	
(Oztas and Iyigun, 2019)	[264]	No statements present	No information to extract	N	N	
(Ozturk et al., 2016)	[265]	No statements present	No information to extract	N	N	
(Padma et al., 2000)	[266]	In the present study, no side effects were noted, and the stimulation was acceptable to all the patients, but the willingness to accept TENS as a mode of relief was equivocal.	Reported no adverse events	Y = 0 tally	N = 0 TENS ONLY	
(Paker et al., 2006)	[267]	In the present study, no serious adverse effects were reported in the intra-articular hylan group or in the TENS group.	Reported no adverse events	Y	N = 0 Tally	One dropout due to worsening pain – not attributable to treatment
(Palmer et al., 2014)	[268]	No statements present	No information to extract	N	N	
(Pan et al., 2003)	[269]	Five patients complained of soreness in the upper arm after ESWT, but this soreness had subsided before their next visit. One patient had cardiac palpitations during the first ESWT session as a result of anxiety but was calm after taking a break. Otherwise, no specific side effect (e.g., hematoma, paresthesia) occurred in either group.	No adverse events recorded in TENS group	Y	Y	Extractable data: (soreness) TENS = 0 events /30 participants ESWT = 5 events / 33 participants
(Park et al., 2015)	[270]	No adverse reactions related to TENS were observed.	Reported no adverse events	Y	N = 0 TENS ONLY	No numerical data
(Patil and Aileni, 2017)	[271]	No statements present	No information to extract	N	N	
(Peacock et al., 2019)	[272]	… and no adverse events were reported in relation to the administration of the Biomodulator, traditional Chinese acupuncture, or TENS device in the study.	Reported no adverse events	Y = 0 tally	N = 0 tally	No numerical data
(Pietrosimone et al., 2009)	[273]	No statements present	No information to extract	N	N	
(Pietrosimone et al., 2011) Secondary Report (Pietrosimone et al., 2010)	[274] Secondary Report [275]	No adverse events were reported to the study personnel regarding TENS or placebo usage.	Reported no adverse events	Y = 0 tally	N = 0 tally	
(Pietrosimone et al., 2020)	[276]	No statements present	No information to extract	N	N	
(Pike, 1978)	[277]	The duration of stimulation, whether intermittent or continuous, is unimportant since neither tachyphylaxis nor side-effects occurred.	Reported no adverse events	Y	N = 0 TENS ONLY	No numerical data
(Pitangui et al., 2012)	[278]	No reports of side effects or dissatisfaction were made, supporting the results of other studies.	Reported no adverse events	Y = 0 tally	N = 0 tally	

Reference	Reference number	Extracted Text	AEs related to TENS	Statement	Extractable Data	Comment
(Pitangui et al., 2014)	[279]	HFT and LFT are safe and effective resources without side effects and presenting good acceptance…..	Reported no adverse events	Y = 0 tally	N = 0 tally	
(Platon et al., 2010)	[280]	The only reported side effect of TENS during the study was discomfort during 1 min of the initial stimulation, which was noticed in some patients.	Slight discomfort during stimulation	Y	N	No numerical data
(Platon et al., 2018)	[281]	Some patients reported an uncomfortable stimulation during the 1 min of the initial stimulation with TENS as a side effect.	Slight discomfort during stimulation	Y	N	No numerical data
(Prabhakar and Ramteke, 2011)	[282]	No statements present	No information to extract	N	N	
(Presser et al., 2000)	[283]	No statements present	No information to extract	N	N	
(Rainov et al., 1994)	[284]	No statements present	No information to extract	N	N	
(Rajfur et al., 2017)	[285]	No statements present	No information to extract	N	N	
(Rajpurohit et al., 2010)	[286]	No statements present	No information to extract	N	N	
(Rakel and Frantz, 2003)	[287]	No statements present	No information to extract	N	N	
(Rakel et al., 2014)	[288]	No statements present	No information to extract	N	N	
(Ramanathan et al., 2017)	[289]	Consort identifies lost to follow due to AE in TENS and placebo group – but numerical data not clear Of note, 11 patients (9.48%) reported popular rash and/or cutaneous blistering around the placement site of adhesive electrodes….. Two patients were withdrawn for persistent cutaneous blistering. Other reasons for withdrawal were … and skin hypersensitivity to adhesive electrodes (n=3, 6.81%) Authors note that withdrawals due to 'device-related discomfort' were in the active group (n=3 6.81%).	Skin irritation/blistering at electrode sites	Y	N	No data extracted because no clear numerical data between the different intervention groups
(Ramos et al., 2018)	[290]	No statements present	No information to extract	N	N	
(Rani et al., 2020)	[291]	No statements present	No information to extract	N	N	
(Ratajczak et al., 2011)	[292]	No statements present	No information to extract	N	N	
(Rawat et al., 1991)	[293]	No statements present	No information to extract	N	N	
(Renovato França et al., 2019)	[294]	No adverse events were observed in this study.	Reported no adverse events	Y = 0 tally	N = 0 tally	
(Reuss et al., 1988)	[295]	No statements present	No information to extract	N	N	
(Revadkar and Bhojwani, 2019)	[296]	No statements present	No information to extract	N	N	
(Ringel and Taubert, 1991)	[297]	No statements present	No information to extract	N	N	
(Robb et al., 2007)	[298]	No statements present	No information to extract	N	N	
(Robinson et al., 2001)	[299]	No statements present	No information to extract	N	N	
(Roche et al., 1985)	[300]	No statements present	No information to extract	N	N	
(Rooney et al., 1983)	[301]	No statements present. Authors state that TENS is 'safe' in the conclusion. No further info.	No information to extract	N	N	
(Rosenberg et al., 1978)	[302]	No complications were observed in this study from the use of TENS and the only morbidity reported has involved skin reactions at the electrode sites	Skin reaction at electrode sites	Y	N	No numerical data
(Rutgers et al., 1988)	[303]	No statements present	No information to extract	N	N	

Reference	Reference number	Extracted Text	AEs related to TENS	Statement	Extractable Data	Comment
(Sadala et al., 2018)	304	No statements present	No information to extract	N	N	
(Sahin et al., 2011)	305	No statements present	No information to extract	N	N	
(Samadzadeh et al., 2017)	306	No statements present	No information to extract	N	N	States in conclusion that TENS is safe but no info on adverse events in main text.
(Sangtong et al., 2019)	307	Table 3 shows adverse events, patient global assessment, and patient satisfaction after treatment. More subjects in the study group had increased knee swelling than subjects in the control group (four patients (6.3%) vs. two patients (2.9%), respectively), but no significant difference (P = 0.430). Table 3 of their report	Joint swelling Rash	Y	Y	Data extracted (joint swelling and skin rash) TENS + US = 4 events / 64 participants US alone = 3 events / 68 participants
(Santamato et al., 2013)	308	None of the patients reported adverse effects during the study period.	Reported no adverse events	Y = 0 tally	N = 0 tally	
(Santana et al., 2016)	309	No statements present	No information to extract	N	N	
(Saranya et al., 2019)	310	No statements present	No information to extract	N	N	
(Sayilir and Yildizgoren, 2017)	311	No statements present	No information to extract	N	N	
(Seo et al., 2013)	312	A total of 7 adverse events that required admission in 6 participants were reported during the study. The adverse events included a traffic accident, acute appendicitis, cellulitis, worsening of lower back pain, shoulder pain, uterine myoma, and spontaneous abortion. There was a possible relationship between the treatment and spontaneous abortion … that occurred 21 days after BTX-A injection and electrical stimulation. She answered “no” to the question “Are you pregnant or do you have a plan for pregnancy?” before study enrolment. The other events were not related to the treatment in this study.	Spontaneous abortion possibly related to treatment. Other adverse events unrelated to treatment.	Y	N	Numerical data not necessarily related to TENS/intervention
(Serry et al., 2016)	313	No statements present	No information to extract	N	N	
(Sezen et al., 2017)	314	We observed a small number of complications in the patients who were administered TENS in our study, but there was no statistically significant difference between the two groups. Table 4 of their report	Authors do not say whether complications were felt to be due to TENS	Y	N	Data related to post-operative complications. Debatably this is related to AE associated with op procedures rather than TENS. We decided not to extract this data because AE from operation reflects efficacy of TENS rather than AE of TENS Not extracted data (complications) TENS (T) = 6 events / 43 Control placebo TENS = 10 events / 44

Reference	Reference number	Extracted Text	AEs related to TENS	Statement	Extractable Data	Comment
						Not definitely attributed to the intervention
(Shahoei et al., 2017)	315	No statements present … Since it has no negative consequences for mothers and their fetus, it is considered a safe pain relief method.	No information to extract	N	N	
(Shehab and Adham, 2000)	316	No statements present	No information to extract	N	N	
(Sherry et al., 2001)	317	No statements present	No information to extract	N	N	
(Shimoji et al., 2007)	318	There were three cases of skin flash at sites of electrode placement in subjects treated with TENS using CPWs, but these disappeared within a day without intervention. No such skin irritation occurred in subjects who received TENS using BMWs. No other complications were reported in both groups. There was also a sham TENS group but no mention of AEs/complications	'Skin flash' (3 cases) in CPW group	Y	Y	Data extracted (skin irritation) TENS (CPWs) = 3 / 9 BMWs (bidirectional modulated sine waves) = 0 events / 11
(Shimoura et al., 2019)	319	No adverse effect was noted with the TENS or sham-TENS treatment.	Reported no adverse events	Y = 0 tally	N = 0 tally	
(Shoukry and Al-Ansary, 2019)	320	Adverse effect during or after the procedure was recorded and treated. Table 3 shows that adverse effects [were significantly less frequent among group-A [TENS + i.v. fentanyl] compared to group-B [i.v. fentanyl]. These statements relate to adverse effects associated with ESWT procedure rather than TENS	O2 desaturation Nausea and vomiting Dizziness	N		The data provides information about effect of TENS on incidence of adverse events associated with ESWT procedure + fentanyl treatment
(Siemens et al., 2020)	321	Two patients experienced an uncomfortable feeling caused by the current, one after IMT and one after PBT One out of 20 (5%) patients perceived the electric current as uncomfortable after the IMT phase and 1/20 (5%) after the PBT phase. No other TENS-related adverse events were reported. Four patients (20%) generally criticized that cables were impractical and one (5%) patient felt disturbed by the electrodes. After testing both TENS modes, 7/20 (35%) patients requested a prescription for the TENS device in order to use TENS after discharge. A usability problem rather than a safety problem was the fact that the main reason for stopping the study after period 2 was the burden in using TENS (5/15, 33%), e.g., because of the disturbing cables of the device (see Online Resource 5 for further reasons).		N	N	Frequency data between placebo and TENS interventions not provided
(Sikiru et al., 2008)	322	The results demonstrated a significant decrease in the NIH-CPSI (P = 0.0002) with no urethral, anal complaints or other side effects	Reported no adverse events	Y = 0 tally	N = 0 tally	
(Silva et al., 2012)	323	No statements present	No information to extract	N	N	
(Silva et al., 2014)	324	No statements present	No information to extract	N	N	
(Sim, 1991)	325	No statements present	No information to extract	N	N	
(Siqueira et al., 2019)	326	No statements present	No information to extract	N	N	
(Sloan et al., 1986)	327	No statements present	No information to extract	N	N	

Reference	Reference number	Extracted Text	AEs related to TENS	Statement	Extractable Data	Comment
(Smania et al., 2005)	328	No statements present	No information to extract	N	N	There was data missing from final analysis but no explanation given
(Smedley et al., 1988)	329	No statements present	No information to extract	N	N	
(Smith et al., 1983)	330	Only one patient noticed any adverse effects from the treatment, a mild skin reaction to the electrode jelly.	Skin irritation in 1 patient.	Y	N	No numerical data to extract
(Smith et al., 1986)	331	No statements present	No information to extract	N	N	
(Sodipo et al., 1980)	332	No statements present	No information to extract	N	N	
(Solak et al., 2007)	333	No statements present	No information to extract	N	N	
(Solak et al., 2009)	334	No statements present	No information to extract	N	N	
(Sonde et al., 1998)	335	No statements present	No information to extract	N	N	
(Stepanovic et al., 2015)	336	Adverse effects were associated with a specific treatment of herpes zoster (n = 5) and analgesics prescribed (n = 20). Most common complication was a bacterial superinfection, in either group there was no serious complication.	Reported no adverse events	Y	N = 0 TENS ONLY	
(Steptoe and Bo, 1984)	337	TENS is almost free from adverse events	No information to extract	N	N	
(Stratton and Smith, 1980)	338	No statements present	No information to extract	N	N	
(Stubbing and Jellicoe, 1988)	339	No statements present	No information to extract	N	N	
(Suh et al., 2015)	340	No statements present	No information to extract	N	N	
(Talbot et al., 2020)	341	No statements present	No information to extract	N	N	
(Tantawy et al., 2018)	342	No statements present	No information to extract	N	N	
(Taylor et al., 1981)	343	No statements present	No information to extract	N	N	
(Taylor et al., 1983)	344	No statements present	No information to extract	N	N	
(Thakur and Patidar, 2004)	345	Side effects were more in the tramadol group in the form of nausea 7%, vomiting 3%, drowsiness 2% and fetal distress 2%, what while in the control group only one percent had fetal distress. Intense group none had any side effects Data in Table 6	Reported no adverse events	Y	Y	Data extracted TENS = 0 events / 100 Control (no intervention) = 1 event / 100 participants (Fetal distress) Also: Tramadol = 14 / 100 participants (nausea, vomiting, drowsiness, fetal distress) – did not add to forest plot to prevent double counting in sub group analysis
(Thomas et al., 1988)	346	No statements present	No information to extract	N	N	
(Thomas et al., 1995)	347	No statements present	No information to extract	N	N	
(Thorsteinsson et al., 1978)	348	No statements present	No information to extract	N	N	
(Tilak et al., 2016)	349	No statements present	No information to extract	N	N	

Reference	Reference number	Extracted Text	AEs related to TENS	Statement	Extractable Data	Comment
(Tokuda et al., 2014)	350	We observed no side effects; thus, TENS may be particularly useful for patients who have liver or kidney disease considering that analgesics are excreted through the kidney.	Reported no adverse events	Y = 0 tally	N = 0 tally	
(Tonella et al., 2006)	351	No statements present	No information to extract		N	
(Topuz et al., 2004)	352	No statements present	No information to extract	N	N	
(Tosato et al., 2007)	353	No statements present	No information to extract	N	N	
(Treacy, 1999)	354	No statements present	No information to extract	N	N	
(Tsen et al., 2000)	355	Some have raised the concern that TENS could interfere with fetal heart rate tracings,1 1 however, this was not witnessed in our review of fetal tracings, nor did we observe any incidents of non-reassuring fetal tracings2 4 subsequent to the CSE placement in either group.	Reported no adverse events.	Y = 0 tally	N = 0 tally	
(Tsen et al., 2001)	356	No statements present	No information to extract	N	N	Authors stated they would record adverse events but no comments included in results or discussion.
(Tsukayama et al., 2002)	357	No adverse events were reported by the evaluator. The therapists reported some transient adverse events, for the EA group: transient aggravation of LBP (1 case), discomfort due to press tack needles (1 case), pain on needle insertion (1 case) and small subcutaneous bleeding (10mm in diameter, 1 case); in the TENS group: transient aggravation of back pain (1 case), transient fatigue (1 case), itching with electrode (1 case). Seven patients in each group did not experience any adverse events.	Increased back pain Transient fatigue Itching with electrode	Y	Y	Data extracted (symptom aggravation, skin reaction, fatigue) TENS = 3 events / 10 participants Electroacupuncture = 4 events / 9 participants
(Tucker et al., 2015)	358	There were no clinically significant adverse events related to TENS in either group. In table 2 of their report	Reported no adverse events	Y = 0 tally	N = 0 tally	
(Tugay et al., 2007)	359	No adverse effects were observed, supporting the findings of the related literature.	Reported no adverse events	Y = 0 tally	N = 0 TENS ONLY	
(Tulgar et al., 1991a)	360	No statements present	No information to extract	N	N	
(Tulgar et al., 1991b)	361	No statements present	No information to extract	N	N	
(Unterrainer et al., 2010)	362	In conclusion, the use of TENS before skin incision and postoperative is noninvasive, safe, simple, and free of systemic side effects in postoperative pain treatment after major spinal surgery.	Reported no adverse events	Y = 0 tally	N = 0 TENS ONLY	
(Unterrainer et al., 2012)	363	No statements present	No information to extract	N	N	
(Upton et al., 2017)	364	No adverse effects reported during the study.	Reported no adverse events	Y = 0 tally	N = 0 tally	
(Vaidya, 2018)	365	However, no negative effects were found with the use of TENS in any stage of pregnancy which supports the finding of our study [9]. No negative effects were reported for any of the patients.	Reported no adverse events	Y = 0 tally	N = 0 tally	
(Vaillancourt et al., 2019)	366	No statements present	No information to extract	N	N	

Reference	Reference number	Extracted Text	AEs related to TENS	Statement	Extractable Data	Comment
(Valenza et al., 2016)	[367]	No adverse effects were reported by any participant after any of the interventions.	Reported no adverse events	Y = 0 tally	N = 0 tally	
(van der Ploeg et al., 1996)	[368]	No adverse side-effects occurred.	Reported no adverse events	Y = 0 tally	N = 0 tally	
(van der Spank et al., 2000)	[369]	No statements present	No information to extract	N	N	
(Vance et al., 2012)	[370]	No statements present	No information to extract	N	N	
(Vitalii and Oleg, 2014)	[371]	No side effects of LF-TENS were seen. Mean gabapentin dose was 1036.36 mg in the study group and 1560 mg in the control group, thus the basic dose was increased by 136.36 mg of gabapentin in the study group and by 560 mg in the control group (P=0.004; Fig. 2). Three patients from the control group reported drowsiness and dizziness on the ninth day of treatment (doses of gabapentin increased to 2700, 2400 and 1800 mg) and one patient reported blurred vision (dose of gabapentin increased to 2700 mg). No side effects of gabapentin were reported in the study group.	Reported no adverse events	Y	N	No data extracted because AEs due to the higher doses of gabapentin in control group. Thus, data reflects TENS efficacy in reducing AEs associated with gabapentin TENS + gabapentin = 0 events Placebo TENS + gabapentin = 4 events (drowsiness + dizziness, blurred vision related to gabapentin)
(Vrouva et al., 2019)	[372]	No statements present	No information to extract	N	N	
(Walker et al., 1991)	[373]	No statements present	No information to extract	N	N	
(Wang et al., 2009)	[374]	No statements present	No information to extract	N	N	
(Warfield et al., 1985)	[375]	There were no complications in either group as a result of TENS. We conclude that TENS is a safe, effective adjunctive therapy for post thoracotomy pain.	Reported no adverse events	Y = 0 tally	N = 0 tally	
(Warke et al., 2004)	[376]	No statements present	No information to extract	N	N	
(Warke et al., 2006)	[377]	No statements present	No information to extract	N	N	
(Yameen et al., 2011)	[378]	No statements present	No information to extract	N		Transcutaneous electrical nerve stimulation is an effective, easy to use and with minimal side effects in patients suffering from trigeminal neuralgia not responding to conventional therapy.
(Yesil et al., 2018)	[379]	No adverse events due to electrotherapy such as irritation or burning of the skin were observed.	Reported no adverse events	Y = 0 tally	N = 0 TENS ONLY	
(Yilmaz et al., 2020)	[380]	We did not observe any side effects or intolerance associated with TENS in our patients. Also, TENS application did not cause any negative changes in vital signs. This result indicates that TENS is easily applied, and its efficacy and safety could help in pain relief for inguinal herniorrhaphy.	Reported no adverse events	Y = 0 tally	N = 0 TENS ONLY	

Reference	Reference number	Extracted Text	AEs related to TENS	Statement	Extractable Data	Comment
(Yilmazer et al., 2012)	[381]	No statements present	No information to extract	N	N	
(Yokoyama et al., 2004)	[382]	No statements present	No information to extract	N	N	
(Yoshimizu et al., 2012)	[383]	No adverse effects or carryover effect were detected.	Reported no adverse events	Y = 0 tally	N = 0 tally	
(Yüksel et al., 2019)	[384]	No statements present	No information to extract	N	N	
(Yurtkuran and Kocagil, 1999)	[385]	No statements present	No information to extract	N	N	
(Zakariaee et al., 2019)	[386]	No statements present	No information to extract	N	N	Mentions that adverse events will be documented but then fails to provide data or clear statement in results nor discussion
(Zhang et al., 2020)	[387]	No statements present	No information to extract	N	N	
(Zhou et al., 2018)	[388]	No adverse events were observed in either of the groups during the 8-week follow-up.	Reported no adverse events.	Y = 0 tally	N = 0 tally	

Legend

Information was identified by searching for text and/or numerical data that referred to adverse events. Information was 'cut and pasted' into this Table. Where available, data on the occurrence of adverse events in each intervention arm was tallied as events (irrespective of severity) per number participants exposed (i.e. number in intervention arm), pooled and meta-analysed. If trial reports included a statement that no adverse events were observed during the study this was identified as such in our table. We only extracted data as 'zero' when the RCT report included numerical data for the presence of at least one adverse event in one of the trial arms and clearly stated that no adverse events had occurred in the other trial arm(s), in line with advice from the Cochrane Collaboration. Y, yes; N, no; TENS, transcutaneous electrical nerve stimulation.

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*Note: Reference numbering in this list relates only to studies cited in this table

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