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Infection Rate of Spinal Cord Stimulators After a Screening Trial Period. A 53-Month Third Party Follow-up

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Objectives: Spinal cord stimulator (SCS) infections are common (2.5–13%) and may cause harm. It is unclear if a screening trial with definitive leads presents an increased infection risk.

Methods: Eighty-four patients with SCS implantations were reviewed from 2004 to May 2008 with a trial period lasting 1–3 weeks.

Results: During the trial one infection (1.2%) occurred with removal of the SCS leads. Three infections (3.6%) occurred after the second stage and were successfully treated with antibiotics. No full implant was explanted due to infection. The more skilled/experienced operator had a lower infection rate (1.8%) than the less skilled/experienced (13%).

Conclusions: Our infection rate (4.8%) compared favorably with our previous survey (7.5%). The reduced number of SCS infections is likely to be due to: strict asepsis, double layer hydrocolloid dressing during the trial, prophylactic antibiotics, operator experience, and patient education. Two-stage procedures with extended trials do not seem to increase the incidence of SCS infections.

Keywords: Infection rate, screening trial period, SCS, spinal cord stimulation

Conflict of Interest: The authors reported no conflicts of interest.

INTRODUCTION

Spinal cord stimulation is an evidence-based treatment for chronic pain (1–5). It is recommended for adults with chronic intractable pain of neuropathic origin by the National Institute for Health and Clinical Excellence of the United Kingdom (6).

Serious complications associated with spinal cord stimulator (SCS) implants, e.g., epidural hematoma (0–0.3%), cerebrospinal fluid leak (0.3–0.5%), permanent neurological harm (paralysis = 0.03%) and death, are rare (7,8). More commonly lead migration (7–21.5%) or damage (6–9%), malfunction of the equipment or failure (4.5–10%), and insufficient pain relief during a trial period (17–25%) occur (3,7–10). The rate of infections associated with the implantation of an SCS is quoted as 2.5–12% (3,8,10–16). SCS device-related infections could lead to neurological harm due to epidural abscesses or meningitis (<1%). An increased infection rate with temporary SCS leads might be associated with prolonged duration and complexity of the operation, the use of permanent internal leads and temporary extensions for the trial period of several days or weeks, and the need of a second operation (13). Infection may lead to wound dehiscence, further surgical interventions, inpatient hospital care, and loss of an expensive implant, so increasing the costs of SCS acquisition.

Spinal cord stimulators can be implanted with or without a screening trial period. There are several ways in which clinicians offer a trial period of SCS and subsequent implantation. The duration of a trial period to predict long-term outcome has not been adequately proven but many of the key confirmatory trials have used a trial period of SCS as part of their selection process (3,7,10,15). In 2008 NICE (6) recommended to perform a temporary trial period before the SCS was implanted permanently. Our method is to employ a two-stage procedure. During stage 1 the permanent cylindrical electrodes are inserted into the epidural space under local anesthesia with on table stimulation. The optimum length of trial is as long as it takes for the patient to be certain that spinal cord stimulation helps to improve pain and function or otherwise. In our practice this is usually achieved within seven days. Although false positives may occur it is not clear if extending the trial prevents this. Our practice is to remain pragmatic and extend the trial if there is patient or physician uncertainty.

During stage 2 the temporary extensions are disconnected and removed.

Other physicians' practice is to perform a trial of SCS using percutaneous electrodes that are anchored to the skin with an adhesive dressing. After a short trial period these are removed by pulling on the leads and the patient is then listed for a single-stage SCS implantation at a later date. The confirmatory trials of SCS do not necessarily make a distinction as to which method is used. It is not known if

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the infection rate with a two-stage implantation during a screening trial period of several days or weeks is different compared with a one-stage implantation following a short temporary trial period and discarded percutaneous leads. Some physicians suggest that a two-stage procedure may result in a higher incidence of SCS implant infection than a single-stage procedure (12,13).

The objective of this retrospective survey is to compare the recent infection rate of SCS (01/2004 to 05/2008) with the infection rate of 18.6% and 7.5% reported in 2002 (17) at the same center and discuss the possible reasons why they are different. Furthermore, it is discussed whether the performance of a two-stage procedure with a screening trial period increases the risk of an infection compared with single-stage implantations that are commonly reported on in the literature.

METHODS

Eighty-four patients were retrospectively and sequentially reviewed during 53 successive months from January 2004 to May 2008. All patients had SCS implanted for the first time with a screening trial period lasting nine days (4–29 days) on average. This includes patients with first- and second-stage implantation and first-stage implantation + trial period + removal. Two operators with different surgical skills (operator 1: more than 300 implantations, operator 2: less than 50 implantations) implanted the SCS. Operator 2 was trained by operator 1.

The surgical procedures were carried out as follows:

The day before the operation patients were asked to shower and clean themselves with water and soap thoroughly. The implantation procedures were performed in an operating theatre under full aseptic conditions (sterile gloves, gown, surgical equipment, drapes and with hat and mask). The operating team consisted of a surgical operator, scrub nurse, runner, pain nurse, physiotherapist, and technician who were familiar with the implantation of SCS. Antibiotics were administered at the beginning and the end of the procedures and frequently a third dose eight hours later. A strict antibiotics policy was not existing, the choice of antibiotics was left to the operator. However, the local practice for the first-stage implantation was to administer cephalosporins to patients from the community and coamoxiclav to patients with a previous hospital visit. Coamoxiclav was most frequently given for the second-stage implantation and vancomycin (Axellia Pharmaceuticals, Copenhagen, Denmark) in case of an existing penicillin allergy (Fig. 1).

The SCS implantation was performed in two stages to determine if the patient is getting satisfactory analgesia during the trial period.

For the first-stage implantation (permanent stimulating electrodes with temporary percutaneous extension leads) the patient was laid prone and awake to achieve satisfactory peripheral topographical mapping by stimulating the posterior column of the spinal cord. The skin was cleaned with 1% chlorhexidine in 70% alcohol and subsequently with iodine-povidone in alcohol. Surgical drapes were applied including an adhesive clear operating drape (Opsite) and 1% lidocaine with 1:200.000 epinephrine was infiltrated into the area of the planned incision site followed by dissection down to the investing fascia just lateral to the spinous process. The epidural space was found with a modified Touhy needle with loss of resistance to air. Under x-ray guidance the stimulating leads were placed in the epidural space and a current was applied to achieve acceptable evoked stimulation in the area of pain perception, which was described as different qualities of paraesthesiae by the patient. After satisfactory topographical placement the electrodes were anchored to fascia with a Medtronic Titan anchoring device and Ethibond non-absorbable sutures. These leads were connected to a temporary extension lead that was tunneled to the flank and exteriorized for the trial period. The wounds were closed with a double layer of Vicryl (Ethicon Inc., Cornelia, GA, USA) and Steristrips (3M Health Care, Neuss, Germany) (Fig. 2a). Hydrocolloid dressings were applied in a sandwich-like technique (Fig. 2b,c). Finally a Mefix dressing (Mölnlycke, Gothenburg, Sweden) was applied (Fig. 2d).

After a screening trial period of 1–3 weeks the second-stage implantation (permanent SCS implant) was carried out either under local anesthesia and sedation or general anesthesia. The dressings were taken down and the exit site inspected for visible signs of infection. As for the first stage, the surgical site was prepared under aseptic conditions and local anesthetic infiltrated. Then the anchoring site wound was opened and inspected for visible signs of infection. A wound swab was taken in the majority of the procedures for microbiological analysis, including sensitivities for positive results. If there were no signs of an infection a subcutaneous pocket was created surgically in the abdominal wall or on the upper buttock area for the implantable pulse generator. The temporary extension leads of the trial period were then disconnected and disposed and the permanent extension leads tunneled and connected between

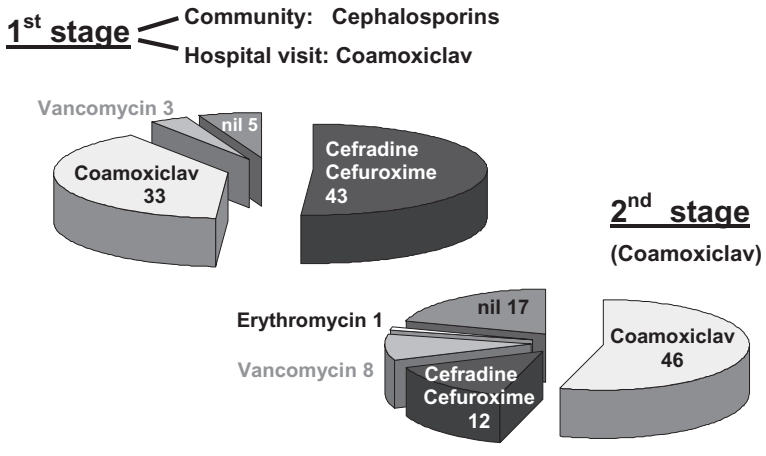

Figure 1. A large variability in the administration of prophylactic antibiotics during first and second stage of SCS implantation is shown.

the already implanted stimulating electrodes and the implantable pulse generator. If there were clinical signs of infection the stimulating electrodes and anchors were completely removed and the procedure abandoned. Finally, all wounds were closed with a double layer of Vicryl and steristrips and dressings applied.

The following data were collected from the case notes: hospital number, age, sex, indication for SCS, past medical history, and the name of the operator. Furthermore, date, level of insertion of the SCS, and prophylactic antibiotics of the first stage, as well as date, prophylactic antibiotics, and microbiological wound swab results for the second stage were noted. Last but not least, clinical and microbiological signs of infection during the subsequent follow-ups post SCS implantation were documented. Follow-up took place between 1–3 months after the second-stage SCS implantation or removal.

An infection was present when a patient showed local or systemic clinical signs of an infection or in combination with a positive microbiology result from the wound swab when the SCS had to be removed or the patient had to be treated with antibiotics.

RESULTS

Forty-four patients were male and 40 female with a mean age of 49.4 years (±12.7 SD). All patients had a temporary first-stage implant and 68 patients (83%) underwent permanent SCS implantations (second stage). In 15 patients (failure rate: 16%) the first-stage SCS was removed because of inadequate pain relief and in one patient (1%) because of an infection of the first-stage SCS. This patient was later implanted having had a successful trial as single full implant procedure.

The peri-operative administration of prophylactic antibiotics was variable. One to three doses of antibiotics were given. Antibiotics were not documented in five cases (6%) of the first-stage implantation and in 17 cases (20%) of the second-stage implantation or removal of SCS electrodes (Fig. 1). Patients coming to the hospital from the community mostly received cephalosporins (43x = 51%) and patients with a previous hospital visit coamoxiclav (33x = 39%) during the first stage. Patients with a penicillin allergy were given a single dose of vancomycin (3x = 4%). For the second stage the preferred antibiotic was coamoxiclav (46x = 55%) due to the previous hospital visit for the first-stage implantation. Twelve patients were given cephalosporins (14%), 8 patients vancomycin (10%), and 1 patient erythromycin (1%) during the second stage.

In 95% of all second-stage implantations wound swabs were taken for microbiological analysis. Wound swabs were not taken when the SCS was removed after the screening trial period due to insufficient pain relief (less than 50%) and if there were no signs of an infection.

Four patients (4.8%) developed a wound infection: Only one infection (1.2%) occurred during the trial period with *Staphylococcus aureus* and the SCS electrode had to be removed. Three infections (3.6%) occurred after the second-stage implantation (two with skin type flora and one with MRSA); they were all successfully treated with antibiotics and did not have to be removed (Table 1). Another four wound swabs showed skin (three) or fecal (one) type flora without clinical signs of an infection and without administration of antibiotics.

Eighty-four SCS were implanted by two consultant anesthetists/pain specialists. In May 2008 Operator 1 had implanted more than 300 SCS (16 years of experience) and operator 2 had implanted less than 50 SCS (seven years of experience). The more skilled operator implanted 61 devices and had only one infection (1.6%). The less skilled operator implanted 23 devices and had three infections (13%) (Fig. 3). The more skilled operator had a lower infection rate.

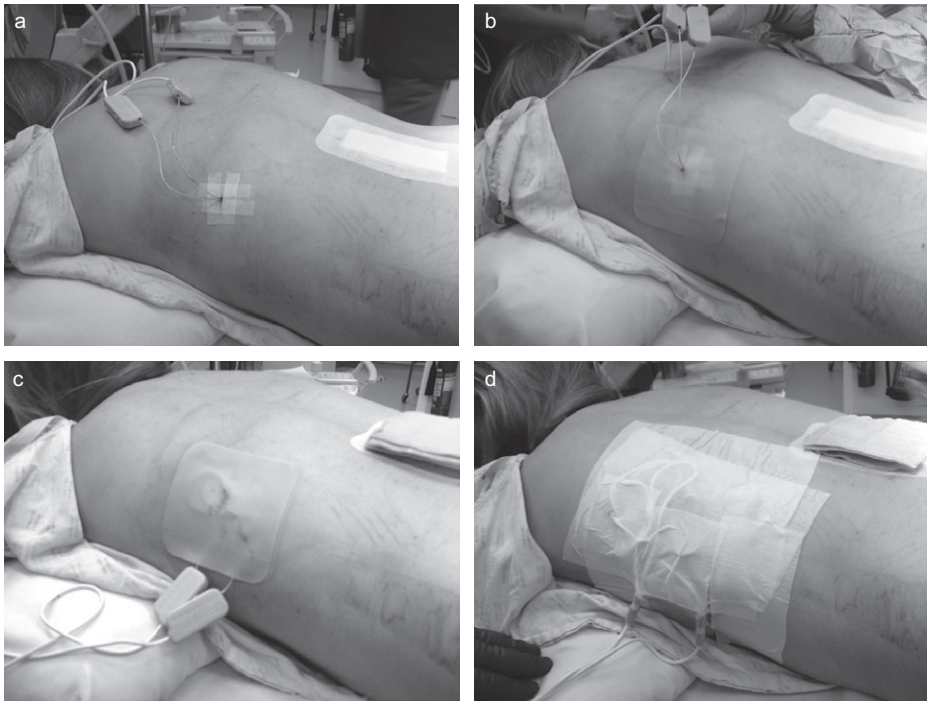

Figure 2. Stepwise application of the occlusive hydrocolloid dressing, double layered at the end of stage 1 implantation. (a) Electrodes anchored, temporary extension attached, tunneled to the flank and Steristrips applied. (b) Layer 1 of occlusive hydrocolloid dressing applied. (c) Layer 2 occlusive hydrocolloid dressing applied (sandwich-like) to protect the wound. (d) Mefix applied to prevent tugging.

Table 1. Infections.

Number of patients/implants		Infections (in %)
84 temporary implants (first stage)		1 (1.2%)
68 permanent implants (second stage)		3 (4.4%)
84 patients (first and second stage)		4 (4.8%)
154 total implants (first and second stage)		4 (2.6%)
Number of infections	Organisms	Removal
1	*Staphylococcus aureus*	Yes (after trial)
1	MRSA	No (antibiotics)
2	Skin type flora	No (antibiotics)

DISCUSSION

The infection rate following first-stage SCS trial at Basildon Hospital was 1.2%. The infection rate following the second stage was 4.4% (Table 1). This compares favorably with the previous audit period published by May et al. in 2002 from the same institution where the infection rate following second-stage implantation had reached 7.5% (17).

May et al. (17) reported an initial infection rate of 18.6% during the trial period (11 out of 59 patients), which lead to the removal of two SCS systems. After the introduction of a revised dressing technique that reduced the movement of the lead extensions and increased patient education concerning skin hygiene and dressing management, the infection rate decreased to 7.5% (3 out of 40 patients). At that time the SCS were all implanted by the same operator.

After the report of May et al. (17) the dressing technique has been improved by the introduction of a hydrocolloid sandwich-like technique (Fig. 2a–d). Furthermore, prophylactic antibiotics were used more aggressively during every surgical procedure (personal communication from SJT). During our survey the same operator had only one infection out of 61 SCS implantations (1.8%), which compares favorably with the above mentioned three infections out of 40 SCS implantations (7.5%). The overall infection rate during our survey can be quoted as 2.6% (4 out of 152 SCS implantations) or 4.8% (4 out of 84 patients). Only one infection out of 84 temporary implants occurred during the trial period (1.2%) and the leads had to be removed. Three infections occurred in 68 permanent SCS implants after the second stage (4.4%) and were successfully treated with antibiotics without removal (Table 1). All infections were superficial and further surgical exploration was not required. These results are similar to the findings of Oakley et al. in 2007 (10) where one infection occurred during 65 SCS trials (1.5%) and 3 after 49 permanent implants (6.1%) with an overall infection rate of 3.5% (4 out of 114 implants). Oakley et al. reported the explantation of three complete systems whereas in our survey none of the full SCS systems had to be removed.

The more skilled operator (more than 300 SCS implants) had an infection rate of 1.6% whereas the less skilled operator (less than 50 SCS implants) had an infection rate of 13%. The level of surgical skills may have contributed to a lower infection rate due to the smoother conduction of the surgical implantation procedures. Prolonged procedures and multiple attempts seem to increase the infection risk (3). The influence of the physician's expertise in patient selection, implant technique, and follow-up care as well as the need of standardization of training in spinal cord stimulation was identified by Henderson et al. in 2009 (18).

Most of the literature only publishes infection rates of the full implant. In our series the second-stage implant rate of infection of 4.4% and the overall infection rate of 2.6% (4 out of 152 SCS implants) or 4.8% (4 out of 84 patients) is within the internationally reported range of 2.5–12% (3,8,10,12–16). Our reported infection rate of 1.2% during the SCS trial period compares favorably with these data and other published data with regards to temporary lead infections (2% (11), 3.8% (3), 1.5% (10), 7.5% (17)).

In 2002 May et al. (17) showed that the increased patient education with regards to hygiene and management of the temporary extension leads during the screening trial period may also have contributed to a decreased infection rate of SCS.

The peri-operative administration of prophylactic antibiotics during this survey showed a great variability. The majority of patients received either cephalosporins or coamoxiclav depending on the origin of the patients (community or previous hospital visit) and the preferred choice of the two different operators. In penicillin allergy either vancomycin or erythromycin was given. In a significant number of patients antibiotics were not documented (Fig. 1).

As a result of this survey a unified antibiotics policy has been implemented that is strictly adhered to: two doses of 1.2 g coamoxiclav are administered before and at the end of both the first- and second-stage SCS implantation. Patients with a documented penicillin allergy receive one dose of 15–20 mg/kg vancomycin in combination with 2 mg/kg gentamicin before the first- and second-stage procedures.

In 2005 "The British Pain Society" (5) recommends a single dose of either a cephalosporin or a combination of vancomycin and gentamicin or teicoplanin and gentamicin 30 min before the incision. Bedder and Bedder (19), Kumar et al., (3) and Follett et al. (13) recommend the administration of prophylactic antibiotics against gram-positive skin flora (*Staphylococcus aureus*, coagulase-negative *Staphylococcus, Enterococcus*) either 1.5 hours before or within 60 min before the skin incision. The routine use of vancomycin is not recommended. Indications for vancomycin or teicoplanin with gentamicin are patients who are MRSA-positive or allergic to penicillin. Torrens et al. (20) described an increased risk of MRSA-infections in patients for SCS implantations and the importance of an MRSA-screening for these patients. Patients with diabetes are at an increased infection risk.

Furthermore, wound swabs for microbiological culture and sensitivity analysis are now routinely being taken during the second-stage implantation or removal of SCS. This will allow for more complete data for future clinical audits.

One of the key elements in the reduction of the infection rate from 18.6% (11 out of 59) to 7.5% (3 out of 40) was the revision of the dressing technique for the SCS trial period in the previous report of May et al. (17). In 2002 and 2003 at the same institution a double layer hydrocolloid dressing was introduced to cover and protect the exit site of the temporary SCS extension leads during the trial period (Fig. 2b,c). This sandwich-like hydrocolloid dressing was used throughout the surveyed period (2004 to May 2008). It may have significantly contributed to the further reduction of the infection rate during the SCS trial from 7.5% (3 out of 40) to 1.2% (1 out of 84) in this survey. After this survey the surgical draping technique was further refined by covering the surgical field with a povidone-iodine impregnated surgical adherent drape. Hydrocolloid dressings have been shown to protect wounds, absorb fluid (21), and provide a physical occlusive barrier to bacterial organisms (22,23). Furthermore, they reduce the movement and prevent the dislocation of the temporary SCS leads at the wound exit site. They also reduce pain at

the wound site and support the healing and recovery process (24,25).

Existing recommendations for the prevention of SCS device infection are as follows:

1. Careful patient selection and preparation (ideally as a day case to minimize the hospital stay) (5,13)
2. Careful preparation of the surgical sites with antiseptic agents and sterile draping (5,13,19)
3. SCS implantation under strict aseptic conditions in an operating room with minimal operating room traffic during surgery (5,13,26)
4. Use of double gloving and minimal touch or no-touch surgical techniques (13,27)
5. Prophylactic administration of antibiotics prior to the incision (3,5,13,19)
6. Avoid incision and suture lines above the implanted devices (13)
7. Closure of the implant site incisions in anatomical layers to prevent the formation of pockets and careful hemostasis (13,19)
8. Application of occlusive and antiseptic wound dressings and dressing changes under aseptic conditions (13,19,21–23)
9. Prompt treatment of infections, considering the removal and or surgical revisions of implanted material (5,13)
10. Frequent surveillance and follow-up, including good documentation and local audit (5)

As a consequence of this audit the following changes were subsequently introduced at our institution:

1. Further improvement of the surgical draping technique with a povidone-iodine impregnated adherent surgical drape instead of a plane adherent drape.
2. Standardized antibiotics policy: two doses of coamoxiclav before and at the end of the surgical procedure each for first- and second-stage SCS implantation. Alternatively, in penicillin-allergic patients, 1 dose of 15–20 mg/kg vancomycin and 2 mg/kg gentamicin pre-operatively for first and second stage.
3. Wound swabs routinely to be taken for microbiological culture and sensitivity analysis during the second-stage SCS implantation as well as for removals of SCS after the screening trial period. This allows the early diagnosis and specific treatment of evolving infections.
4. Standardized documentation for the implantation of SCS and follow-up.
5. Sharing of best surgical practice with colleagues.
6. Saline irrigation or washout of anchor site wound at time of second stage.

CONCLUSIONS

As a result of our survey the following factors were associated with a decreased infection of implantated SCS:

1. Strict aseptic surgical technique (13) with double skin preparation (1% chlorhexidine followed by povidone-iodine).
2. Application of a double layer hydrocolloid dressing (sandwich-like technique) after first-stage implantation for the screening trial period (Fig. 2) compared favorably with the results of May et al. at the same institution in 2002 (17).

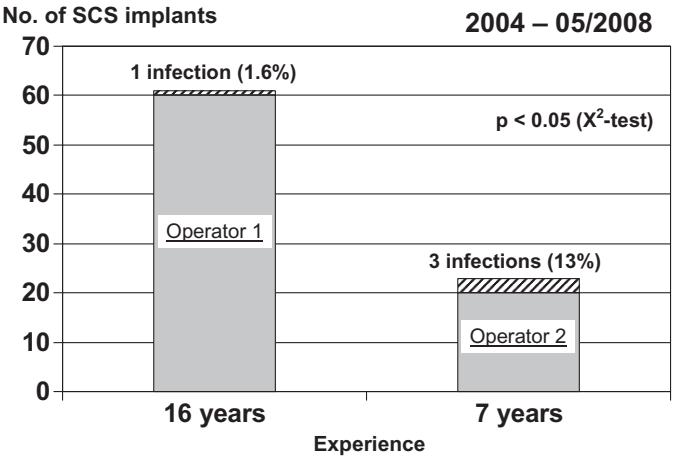

Figure 3. The more skilled operator 1 (>300 SCS implantations) had a lower infection rate with 1.6% (1 out of 61 patients) than the less skilled operator (<50 SCS implantations) with 13% (3 out of 23 patients).

3. Increased patient education and awareness (17).
4. A higher lever of technical skills and experience of the surgical operator (Fig. 3).
5. Routine peri-operative administration of antibiotics (Fig. 1) (3,5,13,19).

According to our findings a two-stage SCS procedure with extended trial period does not seem to increase the incidence of SCS infections above expected levels.

The risk of infection should not be used as a reason to avoid the technique of two-stage spinal cord stimulation by skilled operators providing adequate preparation, environment, wound management, prophylactic antibiotic and surgical dressing policies are followed.

Authorship Statements

Dr. J. Rudiger designed the study under supervision of Dr. Simon Thomson. Dr. J. Rudiger conducted the data collection and analysis and wrote the manuscript draft with input of Dr. Simon Thomson. Funding was not needed for this study. All authors approved the final manuscript.

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COMMENTS

The complication of infection can be a disaster in the patient undergoing spinal cord stimulation. The follow up study by Rudiger and Thomson shows an important improvement in their infection rates for a screening trial of implantable stimulation devices. They attribute their improvement in outcomes to a change in technique, change in antibiotic therapy, and strict asepsis.

The other issue that one must consider is the length of the trial. In the experience of many in the United states where trialing is often done for 72 hours or less the complication of infection is very rare. Obviously, the length of trial with an exposed external lead may lead to an increase in infection. It is critical that we examine the ideal length of trial lead insertion. If we can shorten the trial with an identical long term success rate it would warrant consideration in most cases.

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The authors have proved that 2 stage implantation does not increase the risk of infection and the use of hydrocolloid dressing along with the experience of the operator have a major influence in reducing the infection rate. A trial period is beneficial in that it eliminates approximately 16% of cases that would have otherwise been implanted, and ultimately failed, had a one stage procedure been followed.

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This is a useful summary of certain "best practices" to reduce the risk of infection complicating spinal cord stimulator (SCS) implantation. The data are consistent with benefit of some of these practices, albeit it overstates the evidence to infer "key elements in the reduction of the infection rate from 18.6% . . . to 7.5%." This implies cause and effect; when simple regression to the mean suffices to explain the observed improvement from an unusually high historic rate in this small case series. Coincidental clusters commonly compel circumspection and corrective behaviour.

"The risk of infection should not be used as a reason to avoid the technique of two stage spinal cord stimulation" further overstates the conclusion to be drawn from this small series. The observed infection rate remains significant, and it may be due in part to staging. More to the point, there are a number of reasons apart from infection to avoid staged implantation. [1]

The authors are to be commended for advocating practices to reduce infection, and they are to be encouraged to develop evidence in support of these and other practices to optimize SCS therapy.

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1. North RB, Shipley J. Practice parameters for the use of spinal cord stimulation in the treatment of neuropathic pain. *Pain Medicine* 8(S4):S200–275, 2007.

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