Intravenous regional anesthesia (Bier’s block) is superior to a peripheral nerve block for painless treatment of plantar hyperhidrosis with botulinum toxin*

To the Editor: Severe focal hyperhidrosis may considerably reduce quality of life. Topical therapies are not consistently effective in patients with severe plantar hyperhidrosis. Recently, botulinum toxin type A (BTX-A) has been demonstrated to be highly effective in reducing focal hyperhidrosis. BTX-A inhibits sweat production by blocking the release of acetylcholine from presynaptic membranes in a local and reversible fashion. However, pain from the intradermal injections is difficult to tolerate, and topical anesthesia methods provide unsatisfactory relief. Invasive local anesthetics used in performing the technique of the administration of intravenous regional anesthetic (IVRA) has been used elsewhere, especially for minor surgical interventions of the extremities. Recently, we have demonstrated that IVRA is an effective and safe procedure for BTX-A treatment of patients with palmar hyperhidrosis. Alternatively, peripheral nerve blockade may be used for sufficient anesthesia. In the present study, IVRA was applied for treatment of plantar hyperhidrosis to investigate its effect on pain relief in comparison to a regional nerve block. The overall subject’s acceptance of the two anesthesia methods was rated by means of a questionnaire.

In a pilot study, 8 patients with excessive plantar hyperhidrosis resistant to any previous therapy were treated with intracutaneous injections of BTX-A (BOTOX, Allergan, Irvine, Calif). A total dose of 100 MU/5 ml NaCl BTX-A was used for each sole. In 5 patients, the technique of IVRA was used for regional analgesia. A venous catheter was inserted in a distal vein on the back of the foot. Then, a tourniquet cuff was placed on the lower leg using an electronic double-cuff system (VBM Medizintechnik, Sulz, Germany). After exsanguination, the tourniquet was inflated to a pressure of 250 to 300 mm Hg, and 40 ml of prilocaine 0.5% (Xyloanalges, AstraZeneca, Wedel, Germany) were injected into the distal vein catheter. Twenty minutes after injection of the prilocaine, BTX-A injections were performed. After an additional 10 minutes the double cuff was slowly (over 3 to 4 minutes) released. Because of possible side effects of the

REFERENCES


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For reprints of this letter contact Barbara Vollert, MD, Department of Dermatology, Eberhard-Karls-University, Liebermeister Str 25, 72076 Tuebingen, Germany. E-mail: barbara.vollert@med.uni-tuebingen.de.
local anaesthetic, blood pressure and ECG status were monitored continuously during the IVRA procedure. In 5 patients, peripheral nerve blocks (a selective ankle block in 2 patients and a popliteal nerve block in 1 patient) were performed in accordance to current standard guidelines.7 Subsequently, pain was rated by the patient scoring: painless (score 0), weak (score 1), moderate (score 2), very painful (score 3). A visual analog scale was used for measurement of acute pain.8 In addition, the overall acceptance of both anesthesia methods was rated by patient scoring: well tolerated (score 0), moderately pleasant (score 1), unpleasant (score 2), not at all tolerated (score 3). Before and 2 weeks after BTX-A injections, the hyperhidrosis was assessed by Minor's test and the hyperhidrosis was quantified by measuring the spontaneous sweat secretion using the Corneometer (Courage & Khazaka Electronic GmbH, Cologne, Germany).

Subjective ratings by the patients have demonstrated that BTX-A injections were less painful (mean, 0.05) in patients anesthetized with IVRA than in those treated by a peripheral nerve blockade (mean, 0.5) (Fig 1). With regard to the overall acceptance of both anaesthesia techniques, IVRA was much better tolerated by the patients (mean, 0.2) than the peripheral nerve block (mean, 1.6) (Fig 1).

BTX-A reduced plantar hyperhidrosis; the spontaneous sweat production measured by the Corneometer declined significantly from 101.6 before to 77.9 2 weeks after the BTX-A injections (Fig 2).

In our report, IVRA was more effective than a peripheral nerve block in reducing the pain experienced upon injections. The technique of IVRA was also a safe anesthesia procedure when used according to standard guidelines; no side effects were observed. The major advantages of Bier's block are reliability and ease of administration. In the present study, IVRA was easily performed by dermatologists confirming previous results of our group.9 Therefore, we suggest that the use of Bier's block is not limited to anesthetists but may also be performed by dermatologists after significant training has been completed and with adherence to a strict protocol.

In addition, the procedure of IVRA was much better tolerated by the patients than was peripheral nerve block. This result was mostly because of the rapid recovery of motor function and sensation after tourniquet release. In using a peripheral nerve block, the outpatient visit was prolonged because of the longer duration of this anesthesia method. This issue is of major relevance for an outpatient procedure such as BTX-A therapy. Moreover, our data demonstrated that BTX-A significantly reduces focal hyperhidrosis, confirming previous reports.15

Hans-Juergen Blaheta, MD
Herbert Deusch, MD
Gernot Russner, MD
Barbara Vollert, MD
Departments of Dermatology and
Anaesthesiology
University of Tuebingen
Liebermeisterstr 25
72076 Tuebingen, Germany
Evidence-based evaluation of photodynamic therapy of actinic keratoses

To the Editor: The article on photodynamic therapy of actinic keratoses (AKs) by Dr Jeffes and colleagues (J Am Acad Dermatol 2001;45:96-104) should have been subtitled, “Improving on therapy outcomes by selective reporting of nonsignificant results.”

In this blinded, placebo-controlled study a total of 36 subjects were treated with photodynamic therapy (PDT) using 20% aminolevulinic acid (ALA) and blue light. Each subject had 2 AKs treated with active PDT, whereas 2 control AKs were treated with vehicle and light. The 36 subjects were divided into 3 arms receiving, respectively, 2, 5, and 10 J/cm² of blue light.

The authors claim that, “with the optimal light dose of J/cm², 88% of the AKs completely cleared 8 weeks after a single photodynamic treatment compared with 6% after treatment with vehicle and light.” What is not mentioned is that the 88% cure rate is based on 16 AKs in 8 subjects. Confidence limits were not provided. To give percentage cure rates based on 16 AKs is clinical and statistical nonsense.

Their 6% clearing with placebo and light was based on the same 8 subjects. In the entire group of 35 subjects available at 8 weeks, 17% of AKs cleared with the vehicle. By selective subgroup sampling, the authors reduced the placebo response from 17% to a more respectable 6%. Does any experienced clinician believe that nearly 1 out of 5 AKs disappears spontaneously in 8 weeks? The explanation for the 17% spontaneous cure rate is obvious. Lesions that were not AKs were being treated as AKs.

The authors point out the response was related to lesion thickness. After one treatment, 77% of grade I lesions (“mild lesions slightly palpable with AKs more readily felt than seen”) had cleared; for grade II lesions (“moderately thick AKs easily seen and felt”), only 52% had cleared. The more clinically significant the AK, the less effective is PDT. Furthermore, the AKs of greatest clinical significance, namely hyperkeratotic and hypertrophic, were excluded because of “previous experience suggesting these did not respond well to PDT.”

PDT of AKs is an involved and painful therapy unsuitable for hyperkeratotic AKs. It has to be evaluated in relation to alternative therapies. I was amazed that the authors concluded that PDT is “an effective treatment for multiple AKs” on the basis of 16 AKs. Their claim, in the summary, of a 6% placebo-curing rate is not correct. Actually, 17% of all treated AKs cleared with the vehicle. The Journal is peer reviewed; were the reviewing peers asleep when this one crossed their desks?

Ernst Epstein, MD
100 S Ellsworth Ave, Suite 707
San Mateo, CA 94401

Reply

To the Editor: The study is the first published multicenter, vehicle-controlled, investigator-blinded phase II trial evaluating photodynamic therapy with aminolevulinic acid (ALA-PDT therapy) of actinic keratoses (AKs). Consistent with any phase II trial, the primary objective was to demonstrate safety, to begin to explore efficacy, and to guide follow-on research. All of these goals were clearly met, as supported by the Food and Drug Administration’s (FDA) acceptance of these data as an important part of the drug’s approval. This study also demonstrates that light dose is important in eliminating AKs treated with ALA, with 2 J/cm² not