Design of the Neuroline Concentric EMG needle A Multicentre, Post-marketing Study

SUMMARY

The objective of the study was to verify the safety and performance of the design of the Ambu Neuroline Concentric EMG needle. The primary endpoint was the signal quality measuring quantitatively the incidence of signal errors during EMG examinations in patients.

The secondary endpoint was the patients' experience of pain during the needle examination measured on a visual analog scale.

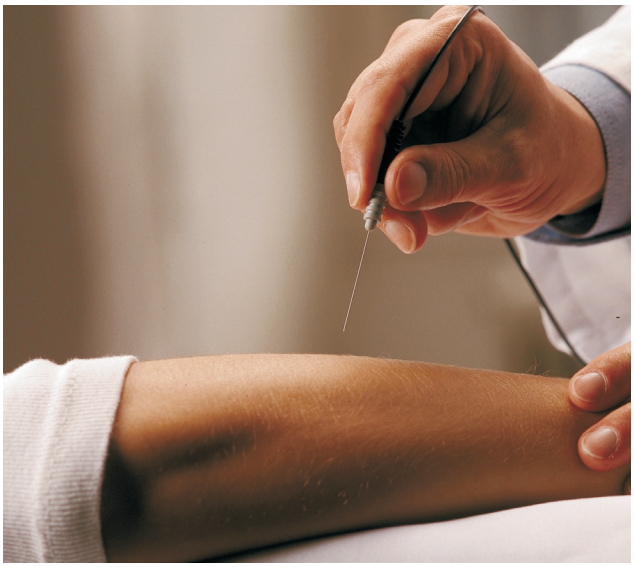
A total of 270 patients were included at 5 centres and 267 (125 men and 142 women) were valid for statistical analysis. The participating centres were: The Cleveland Clinic, Cleveland, Ohio, USA; Neuro-Stat, San Antonio, Texas, USA; Glostrup Amtssygehus, Glostrup, Denmark; Scientific Hospital San Raffaele, Milano, Italy; St. Augustinus Krankenhause, Düren, Germany.

A clear muscle/nerve signal was observed in 98.9% of all examinations. In 1.1% of the examinations a clear muscle/nerve signal was thus not observed during the examination (signal error). However, this rate is significantly better than the success criterion of 10% ($p<0{,}0005$, Binomial test) and the result of an earlier clinical study on the previous version of the Ambu Neuroline Concentric EMG needle. The signal was considered very good or good by the examiners in 99.7% of the examinations and the noise was considered unacceptable in only 1% of the examinations.

The patients' experiences of pain measured on a Visual Analog Scale (100 mm; 0=no pain – 100=worst imaginable pain) were (reported as mean, (median)): Insertion of needle 21(14), repositioning of needle 29(23), contraction of muscle 30(22), and withdrawal of needle 11(5).

Compared to an earlier study on concentric needles and comparable studies found in the literature this may, other things being equal, be considered a low pain score.

In conclusion, the aim of a low signal error and a low pain score was fulfilled in this investigation of safety and performance of the Ambu Neuroline Concentric EMG needle.



INTRODUCTION

In 2004 Ambu A/S launched an improved version of the Neuroline® Concentric EMG needle electrode. In order to verify safety and performanceof the improved needle a clinical study was performed.

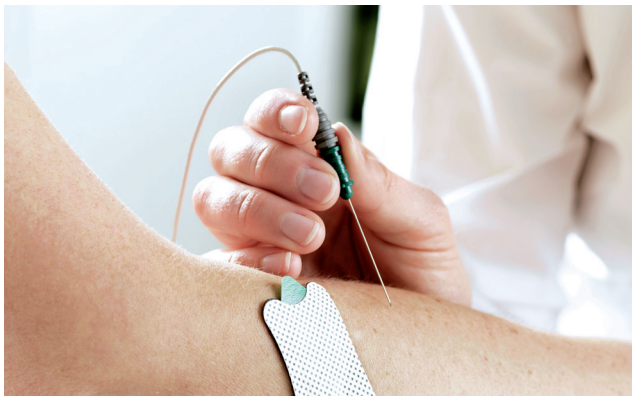
AIM

The aim was to investigate the signal quality and the patients' experience of pain.

MATERIALS

The Neuroline® Concentric EMG needle is a disposable, single use (one patient) bipolar concentric needle electrode, consisting of a silver core wire located inside the lumen of a stainless steel cannula. The sizes used in the clinical study were: a) length 38mm (1.5"), and needle diameter 0.45mm (26G) and b) length 25mm (1.0"), and needle diameter 0.30mm (30G).

The tip features a back-bevel cut, exposing the central wire as an oblique, elliptical surface with a recording area of 0.02 and 0.07mm² for the 25/30 and the 38/26 needle, respectively.



DESIGN OF THE STUDY

The study was a multinational, non-comparative study with 5 participating centres:

- The Cleveland Clinic, Cleveland, Ohio, USA, Dr. Kamal Chemali
- Neuro-Stat, San Antonio, Texas, USA, Dr. Peter Tarbox, Tech. Art Hahn
- Glostrup Amtssygehus, Glostrup, Denmark, Dr. Kjeld Visti Andersen
- Scientific Hospital San Raffaele, Milano, Italy, Dr. Ubaldo Del Carro
- St. Augustinus Krankenhause, Düren, Germany, Dr. Volker Milnik

The study was approved by the Ethics Committee/IRB's in Germany and US and informed consent was obtained from all patients. No Ethics Committee approvals were needed in Italy and Denmark.

PATIENTS

The study patients were patients referred to EMG examinations in the clinical neurophysiology departments of the participating hospitals. A total of 270 patients were included and 267 were valid for statistical analysis. Patients with chronic pain, hypersensitivity, fibromyalgia or on anticoagulation treatment were excluded from the study.

DEMOGRAPHIC DATA:

Gender: Males 46.8%, females 53.2% Mean age: 52.1 (18-84) Ethnic origin: Caucasian 82.2%, Hispanic 16.3%, Turkish 1.2%, Asian 0.4% Method

The investigator (physician) or a neurology technician (USA) performed the EMG examination according to the normal procedure at the department. No additional procedures than the EMG were performed with the patient during the examination.

All recordings obtained during the examination were recorded and documented in the Case Report Form. In the Case Report Form a subjective evaluation of pain at insertion, manipulation and withdrawal of the needle was made by the patient. A Visual Analogue Scale (VAS) was used for the evaluation.

PAIN

Studies on other needles have shown mean pain scores in the range of 40 mm[1,2] and 6.78mm[3] (on a scale from 0-10 mm), so a mean pain score of 23 mm can be considered a low pain score. Many things, such as age, gender, insertion technique, type of needle, physical surroundings, examiner etc. may however influence perception of pain and make it difficult to compare results from different studies.

CONCLUSION

Evaluation of needle quality measured as signal quality and handling, indicates a high needle quality. Pain measurements support this conclusion based on the low pain score compared to results from other studies[1,2,3]. In conclusion, the aim of a low signal error and a low pain score was fulfilled in this investigation of safety and performance of the Neuroline Concentric EMG needle.

REFERENCES

1. Strommen JA, Daube JR: Determinants of pain in needle electromyography.
Clin Neurophysiol.2001 Aug;112:1414-18.

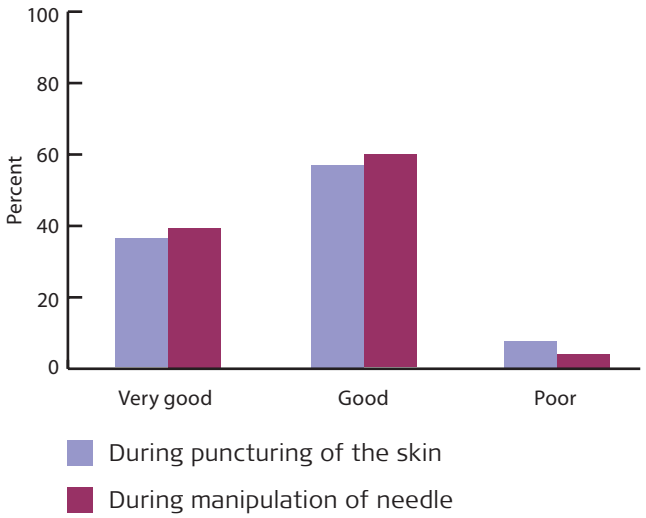
2. Walker WC, Keyser-Marcus L.A., Johns JS, Seel RT: Relation of electromyography-induced pain to type of recording electrodes. Muscle Nerve 2001;24:417-420.

3. Richardson JK, Evans JE, Warner JH: Information Effect on the Perception of Pain During Electromyography. Arch Phys Med Rehabil. 1994;75:671-5.

RESULTS

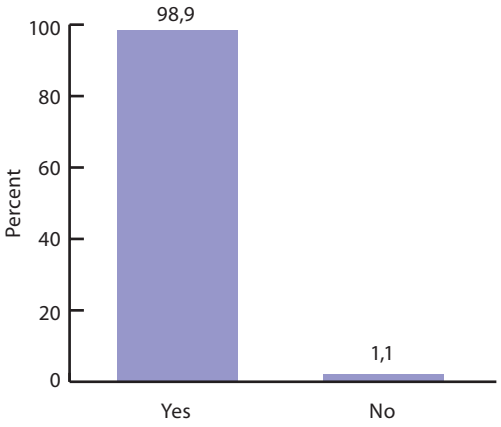
HANDLING

Flexibility of the needle:

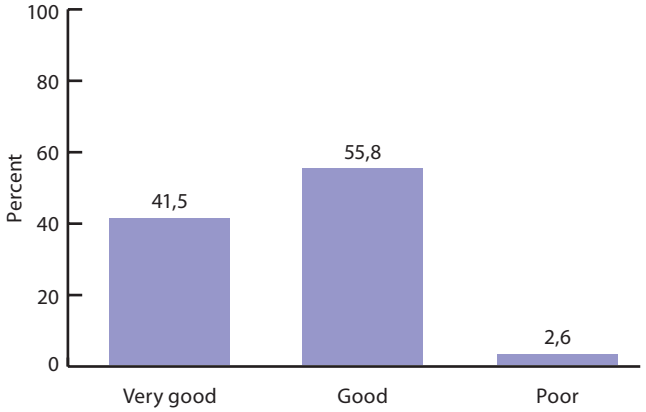


SIGNAL QUALITY

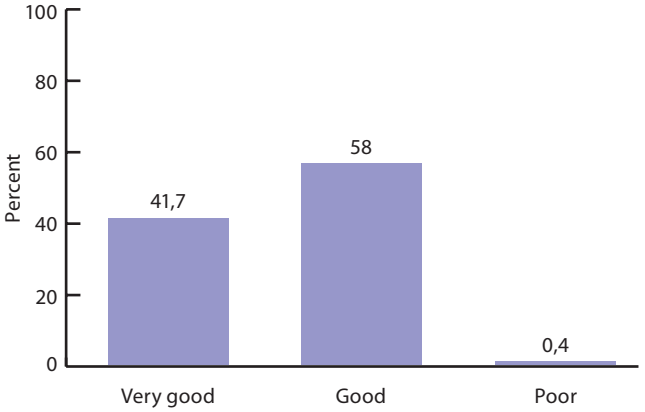
Clear muscle/nerve signal:



Handling of the needle during examination:

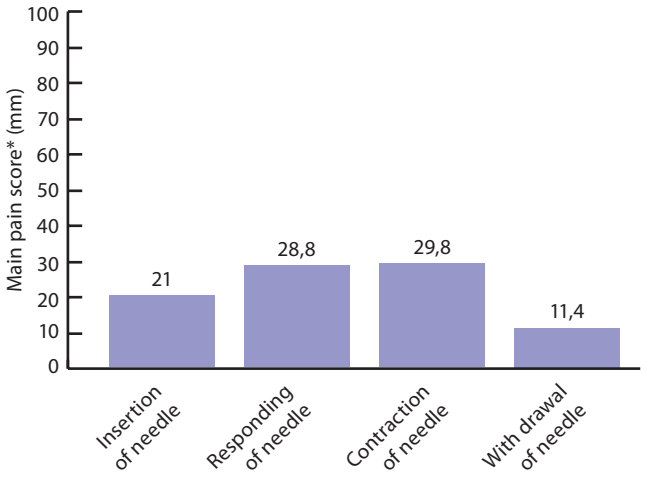


Experience of the signal:



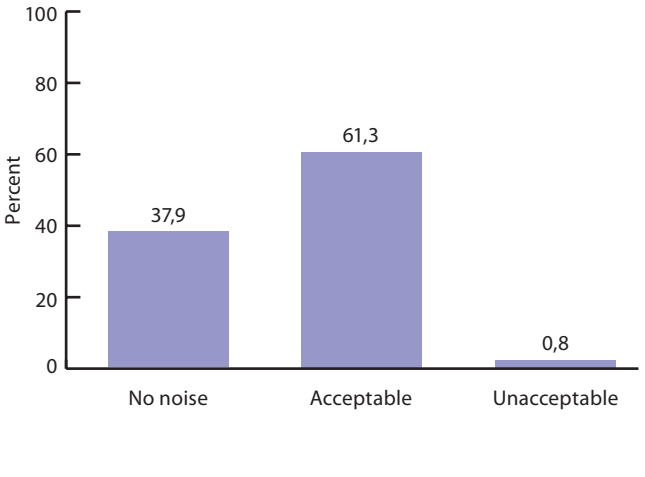
PAIN

Sensation of pain:



HANDLING

Experience of the noise signal:



*Visual analogue scale (VAS) ranging from "pain threshold" (0 mm) to "worst imaginable pain" (100 mm).