

ERN eUROGEN registry

Report on Expertise Area 2.1

INTRODUCTION

This report entails the ERN eUROGEN registry retrospective analysis of the Expertise Area 2.1: Complicated and complex pelvic floor disorders: AMS800. This report aims to give insight in the current clinical practices using the Clinical Practice Snapshot data about the patients entered.

As retrospective data entry is still ongoing for the majority of HCPs, not all HCPs have reached the minimum of 30 retrospective patients per Expertise Area, yet. As patient numbers are not similar, the results cannot be equally compared between HCPs, but the analyses give an indication of trends.

Please keep in mind these reports are meant to inform you about some general treatment characteristics using the Clinical Practice Snapshot data, not to perform in-depth statistical analyses. If you have any suggestions about information to add to these reports, or to delete because the information is not relevant, please let us know and it will be taken into account for the next report.

EA 2.1; COMPLICATED AND COMPLEX PELVIC FLOOR DISORDERS: AMS800

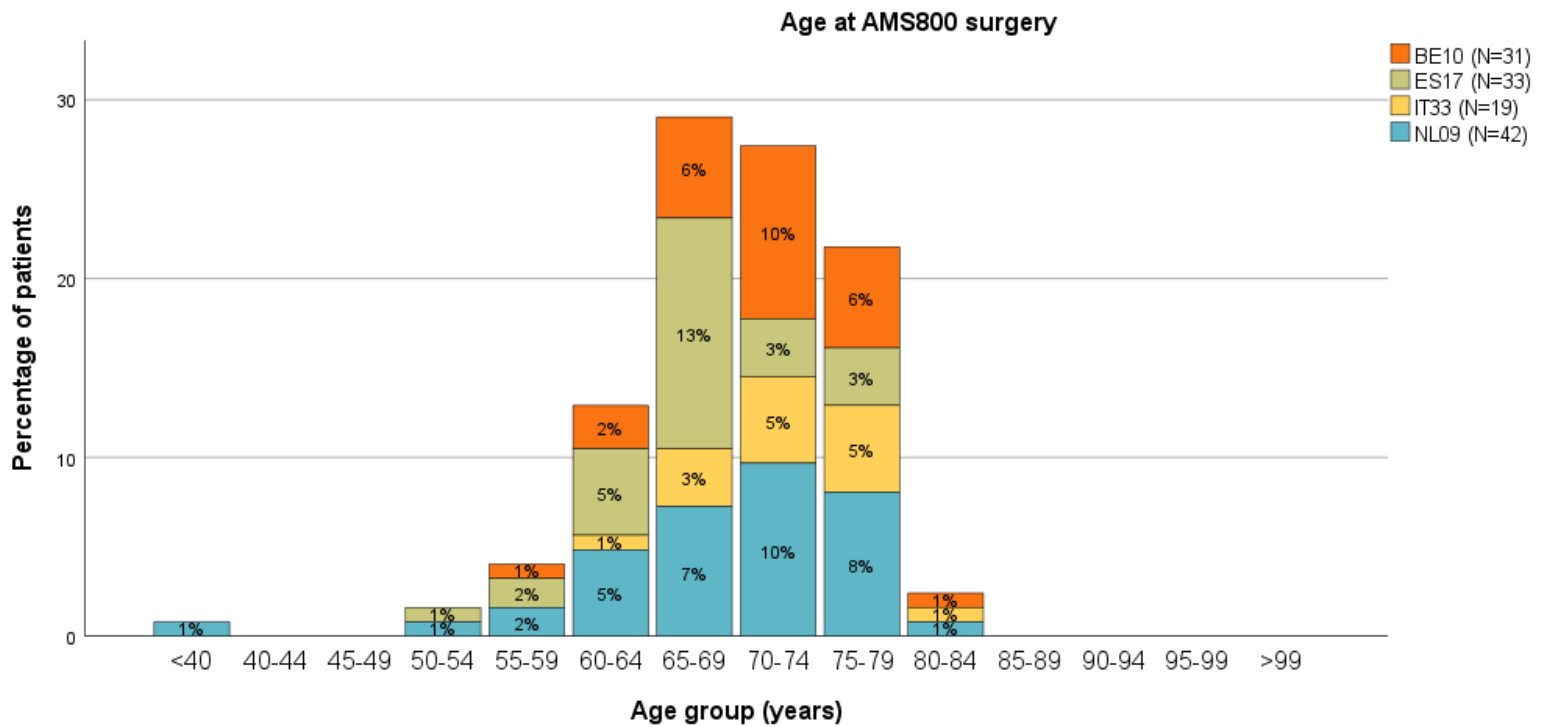
Descriptive statistics

The table below provides an overview of the descriptive statistics for patients from Expertise Area 2.1, complicated and complex pelvic floor disorders treated with an AMS800 device. Corresponding figures were made of the variables, and they are displayed on the next pages.

| | Total N=125 | Belgium BE10 (N=31) | Spain ES17 (N=33) | Italy IT33 (N=19) | Netherlands NL09 (N=42) |
|--|-----------------------|------------------------|-----------------------|-----------------------|----------------------------|
| AMS800 implant surgery | | | | | |
| Age at 1 st surgery; Median (range) | 70.0 years (25;83) | 72.0 years (58;80) | 68.0 years (54;77) | 73.5 years (64;81) | 70.0 years (25;83) |
| Activation of AMS800 device | | | | | |
| Within 6 weeks; N (%) | 91 (72.8%) | 29 (93.5%) | 5 (15.2%) | 17 (89.5%) | 40 (95.2%) |
| Later; N (%) | 34 (27.2%) | 2 (6.5%) | 28 (84.8%) | 2 (10.5%) | 2 (4.8%) |
| Complications after surgery | | | | | |
| Within 6 weeks | | | | | |
| No complications; N (%) | 95 (76.0%) | 26 (83.9%) | 29 (87.9%) | 16 (84.2%) | 24 (57.1%) |
| Complications; N (%) | 30 (24.0%) | 5 (16.1%) | 4 (12.1%) | 3 (15.1%) | 18 (42.9%) |
| Pain at prosthesis site; N (%) | 23 (76.7%) | 2 (40.0%) | 2 (50.0%) | 2 (66.7%) | 17 (94.4%) |
| Fever (>38°C); N (%) | - | - | - | - | - |
| Redness and swelling; N (%) | 8 (26.7%) | 4 (80.0%) | 1 (25.0%) | - | 3 (16.7%) |
| Retention; N (%) | 7 (23.3%) | 2 (40.0%) | 1 (25.0%) | 1 (33.3%) | 3 (16.7%) |
| Within 3 months | | | | | |
| Unknown if complications; N (%) | 2 (1.6%) | 1 (3.2%) | - | - | 1 (2.4%) |
| No complications; N (%) | 105 (84.0%) | 29 (93.5%) | 30 (90.9%) | 18 (94.7%) | 28 (66.7%) |
| Complications; N (%) | 18 (14.4%) | 1 (3.2%) | 3 (9.1%) | 1 (5.3%) | 13 (31.0%) |
| Pain at prosthesis site; N (%) | 11 (61.1%) | 1 (50%) | 1 (33.3%) | - | 9 (69.2%) |
| Fever (>38°C); N (%) | 1 (5.6%) | - | 1 (33.3%) | - | - |
| Redness and swelling; N (%) | - | - | - | - | - |
| Mechanical failure; N (%) | 6 (33.3%) | - | 1 (33.3%) | 1 (5.3%) | 4 (30.8%) |
| Other characteristics | | | | | |
| Using pads; N (%) | 60 (48.0%) | 8 (25.8%) | 22 (66.7%) | 15 (78.9%) | 15 (35.7%) |
| Patient can operate pump; N (%) | 117 (93.6%) | 30 (96.8%) | 31 (93.9%) | 18 (94.7%) | 38 (90.5%) |

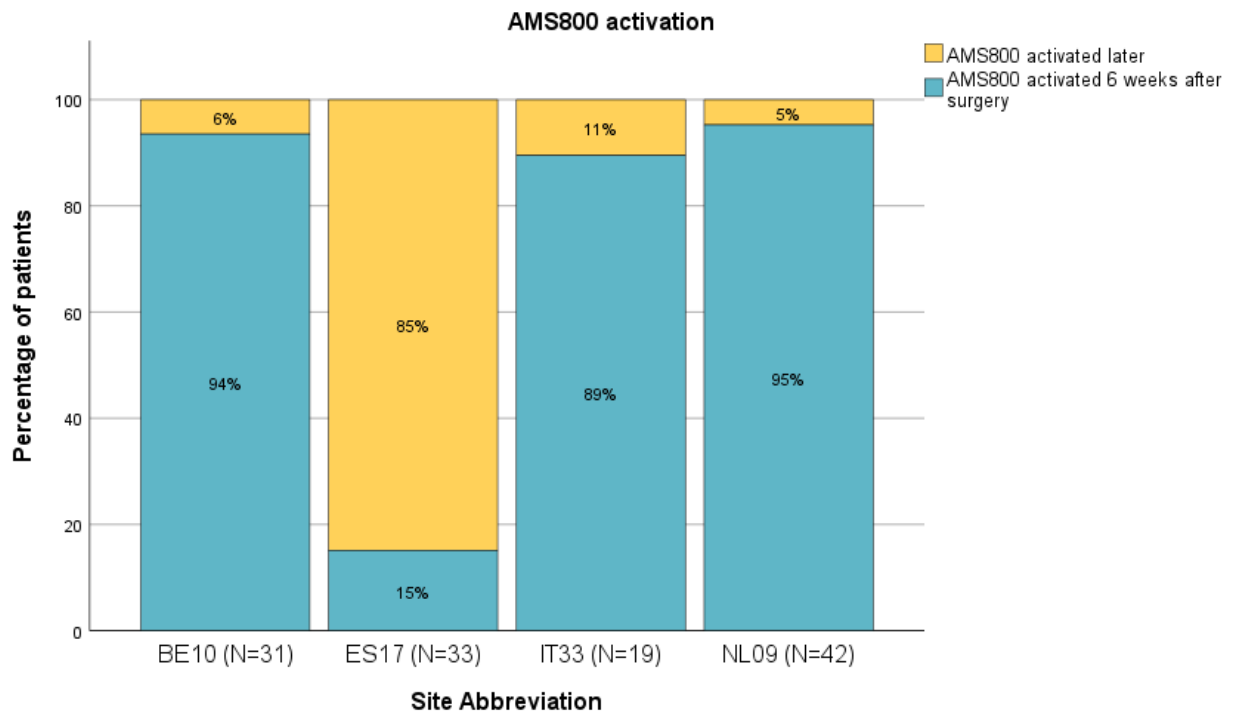
AMS800 implant surgery

The majority of patients received their AMS800 device when they were between 65 and 79 years old, with a peak at the age of 65-69 years.



Activation of AMS800 device

All patients had their AMS800 device activated, most activations took place within 6 weeks after surgery, except at ES17.

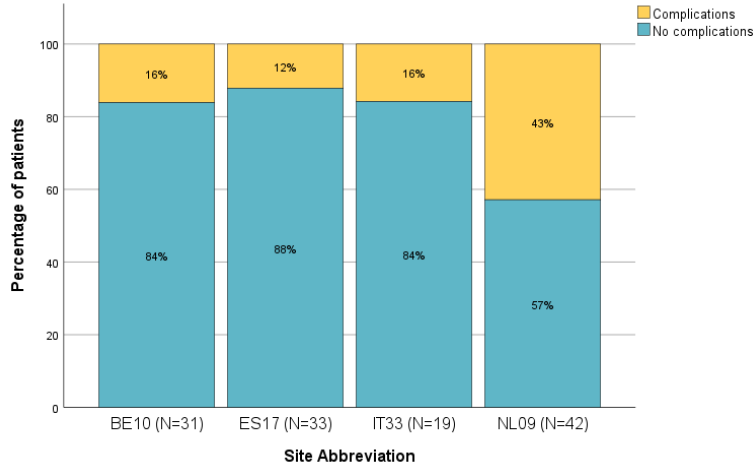


Complications after surgery

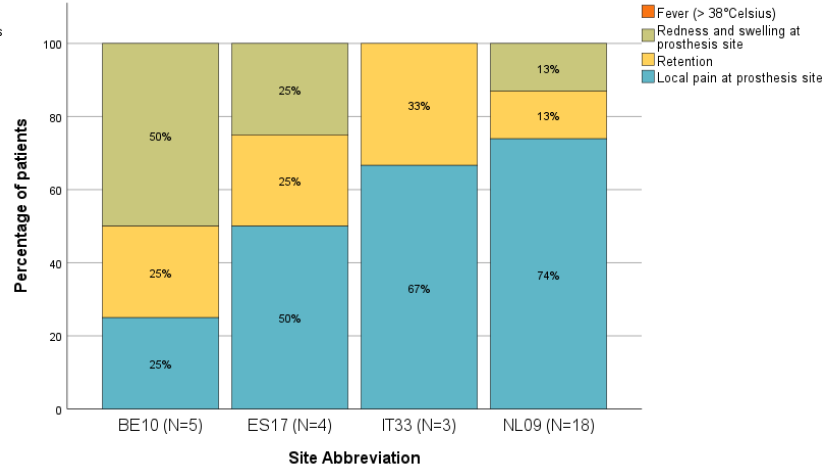
Within 6 weeks

Most patients did not experience any complications from their AMS800 surgery within 6 weeks. If patients had complications, the most frequent complication was local pain at prosthesis site. There were no patients with fever after surgery.

Complications within 6 weeks of AMS800 surgery



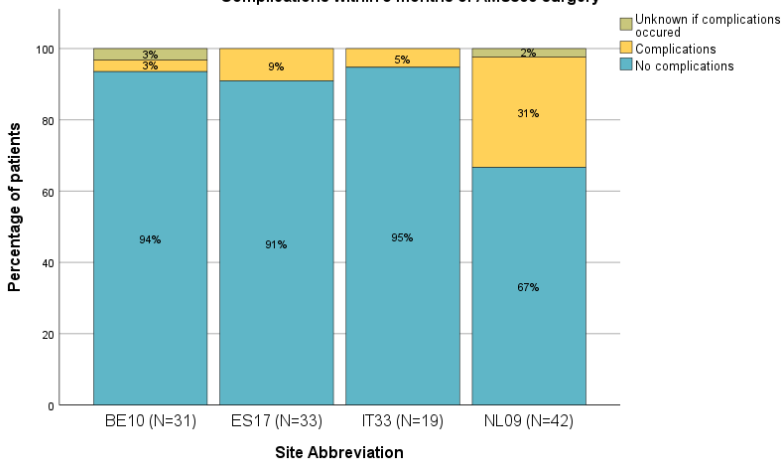
Type of complications within 6 weeks of AMS800 surgery



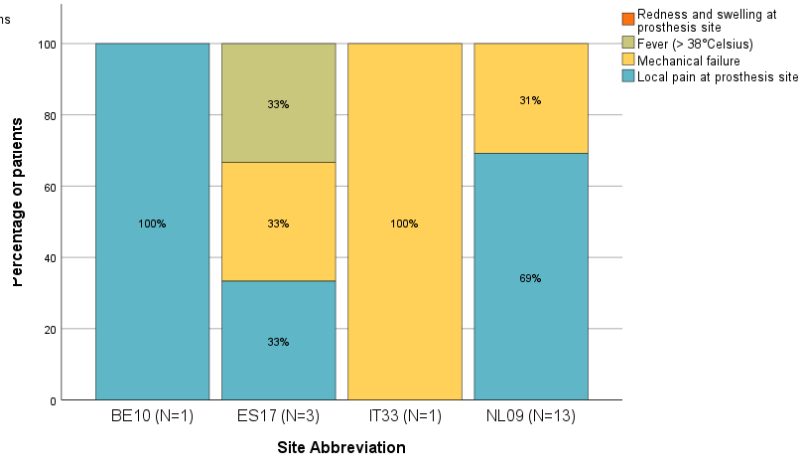
Within 3 months

Again, most patients did not experience any complications within 3 months after the surgery, and the most reported complication was local pain at prosthesis site. There were no patients who experienced redness and swelling at the prosthesis site anymore.

Complications within 3 months of AMS800 surgery



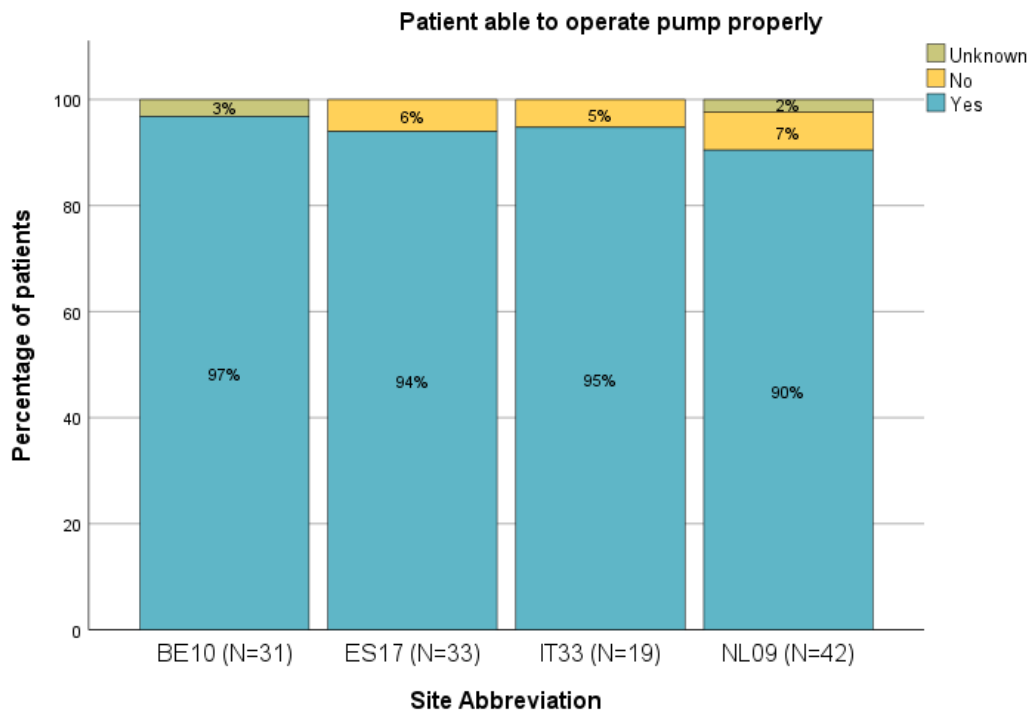
Type of complications within 3 months of AMS800 surgery



Other characteristics

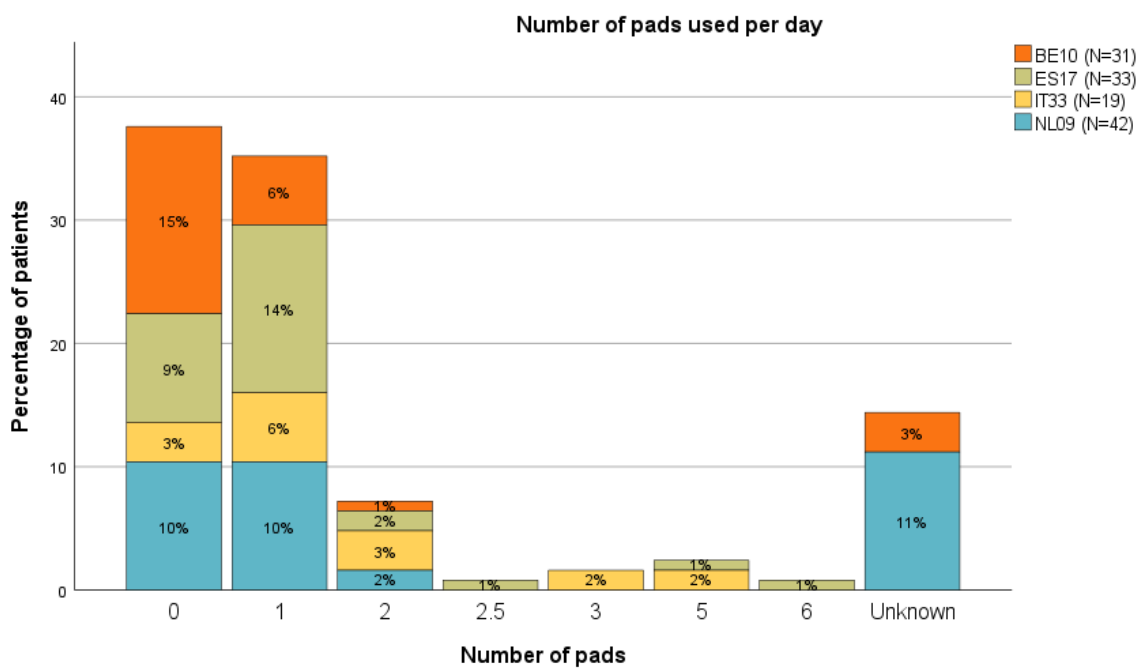
Patient can operate pump

Most patients were able to operate their pump properly.



Using pads

From the patients of whom this information is available, most don't use pads. If they do use pads, the majority of the patients need one pad per day.





Network
Urogenital Diseases
(ERN eUROGEN)

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