ERN eUROGEN registry
Report on Expertise Area 2.1

INTRODUCTION

This report entails the first 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.

The Clinical Practice Snapshots should only contain data about the first year of treatment. However, sometimes information outside the 1-year window was added, and at other times, the dates are unknown. If this occurs, we interpreted this variable for this patient as 'No', 'Not performed', or 'Unknown'. An example: A patient had the AMS800 surgery at 23-01-2021 (start treatment), and a revision took place at 08-02-2022 (more than a year after the start of treatment). This revision should not be entered in the Clinical Practice Snapshot of the ERN eUROGEN registry. If this information was there, we interpreted it as 'No revision'. If it was indicated that the revision took place but the date is unknown, we interpreted the variable as 'Unknown', because we don't know if this revision took place within a year from the start of treatment.

Furthermore, 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. Therefore, 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 analysis. 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

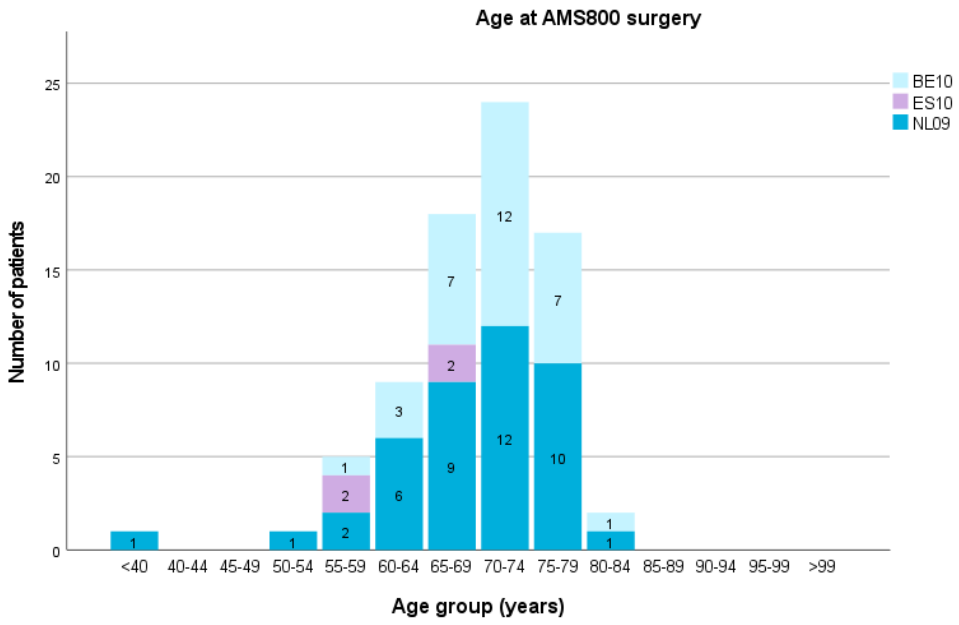
Descriptive statistics

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=77	Netherlands NL09 (N=42)	Belgium BE10 (N=31)	Spain ES10 (N=4)
AMS800 implant surgery				
Age at 1st surgery; Median (range)	71.0 years (25;83)	70.0 years (25;83)	72.0 years (58;80)	64.0 years (58;69)
Activation of AMS800 device				
Within 6 weeks; N (%)	72 (93.5%)	40 (95.2%)	29 (93.5%)	3 (75.0%)
Later; N (%)	5 (6.5%)	2 (4.8%)	2 (6.5%)	1 (25.0%)
Complications after surgery				
Within 6 weeks				
No complications; N (%)	52 (67.5%)	24 (57.1%)	26 (83.9%)	2 (50.0%)
Complications; N (%)	25 (32.5%)	18 (42.9%)	5 (16.1%)	2 (50.0%)
Pain at prosthesis site; N (%)	19 (76.0%)	17 (94.4%)	2 (40.0%)	-
Fever (>38°C); N (%)	-	-	-	-
Redness and swelling; N (%)	9 (36.0%)	3 (16.7%)	4 (80.0%)	2 (100%)
Retention; N (%)	5 (20.0%)	3 (16.7%)	2 (40.0%)	-
Within 3 months				
No complications; N(%)	61 (79.2%)	28 (66.7%)	29 (93.5%)	4 (100%)
Complications; N (%)	16 (20.8%)	14 (33.3%)	2 (6.5%)	-
Pain at prosthesis site; N (%)	10 (12.2%)	9 (64.3%)	1 (50%)	-
Fever (>38°C); N (%)	-	-	-	-
Redness and swelling; N (%)	-	-	-	-
Mechanical failure; N (%)	4 (4.9%)	4 (28.6%)	-	-
Other characteristics				
Using pads; N (%)	25 (32.5%)	15 (35.7%)	8 (25.8%)	2 (50.0%)
Patient can operate pump; N (%)	72 (93.5%)	38 (90.5%)	30 (96.8%)	4 (100%)
Patient had revision(s), N (%)	9 (11.0%)	6 (14.3%)	3 (9.7%)	-

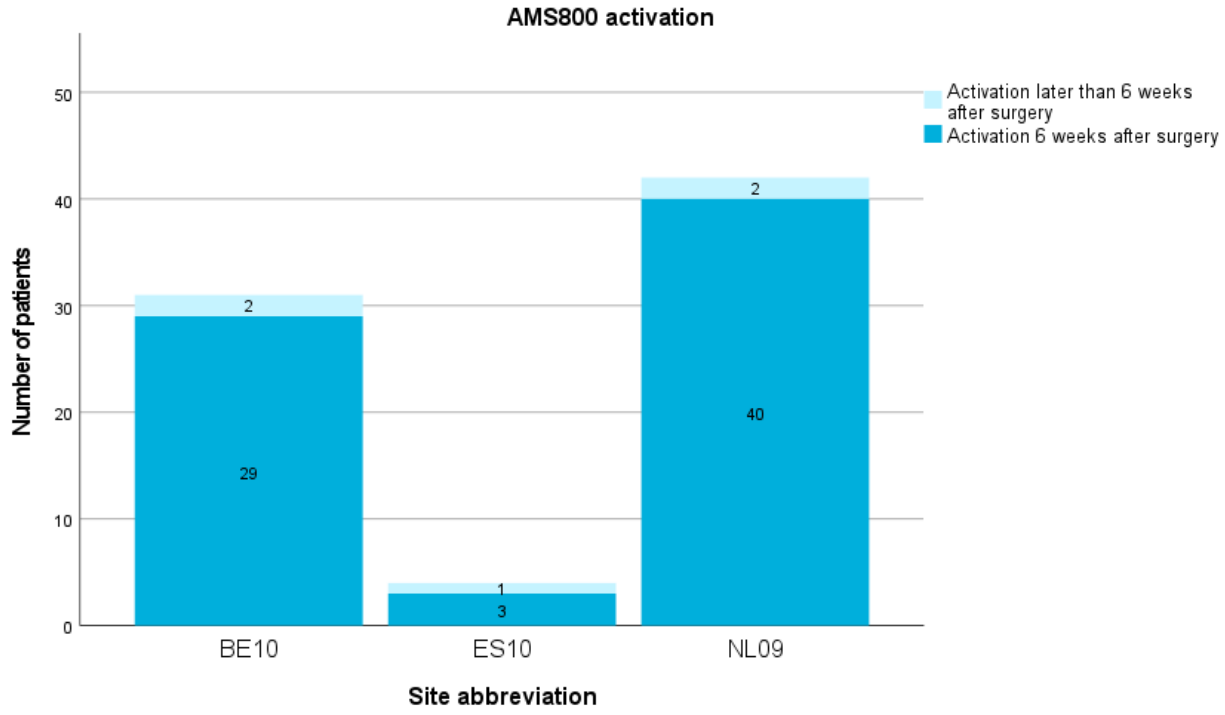
AMS800 implant surgery

The majority of patients received their AMS800 device when they were between 65 and 79 years old, with a peak at the age of 70-74 years.



Activation of AMS800 device

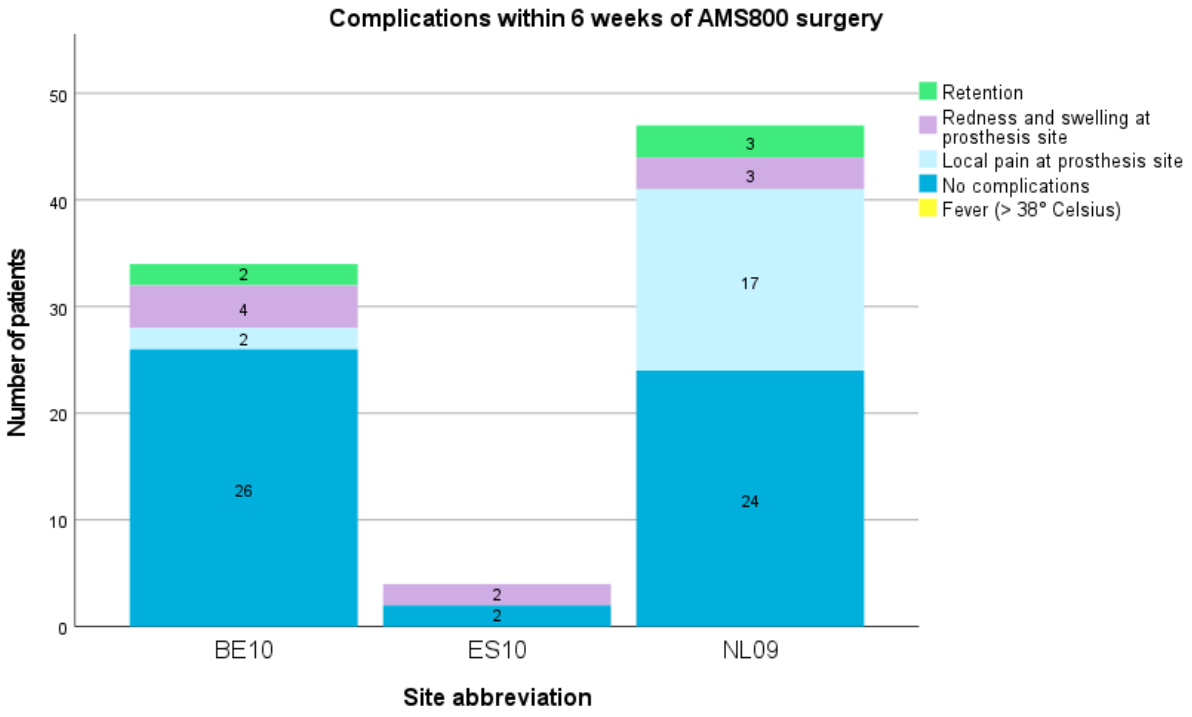
All patients had their AMS800 device activated, most activations took place within 6 weeks after surgery.



Complications after surgery

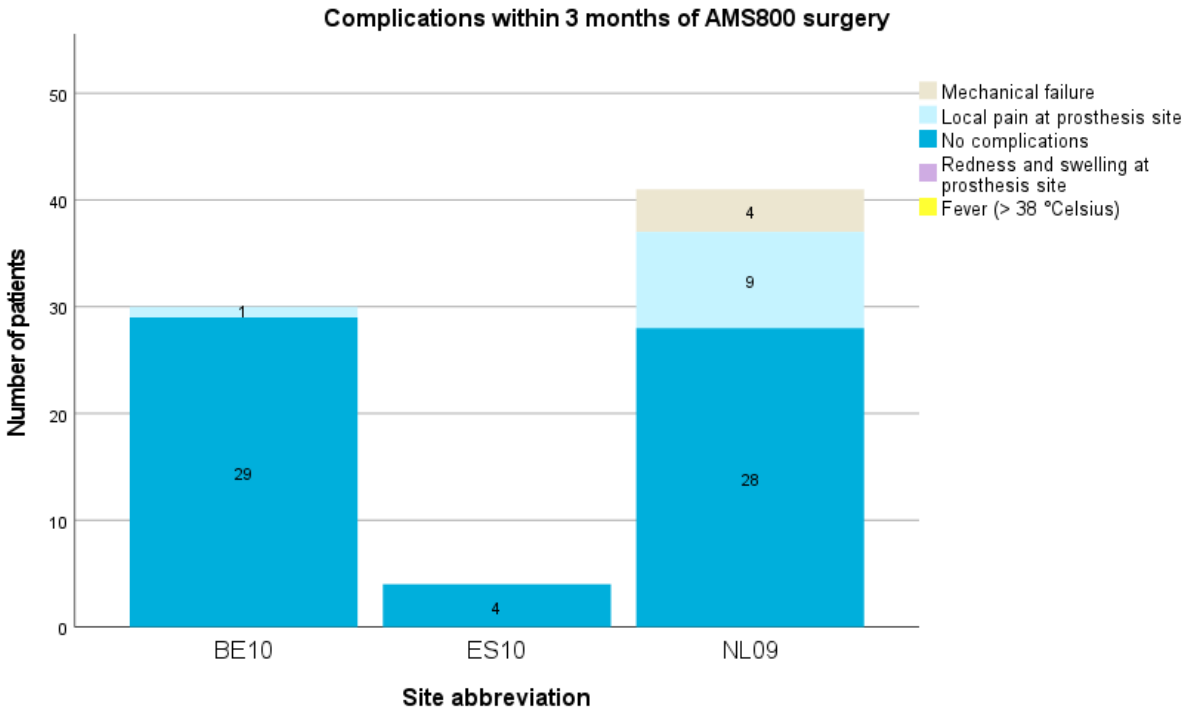
Within 6 weeks

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.



Within 3 months

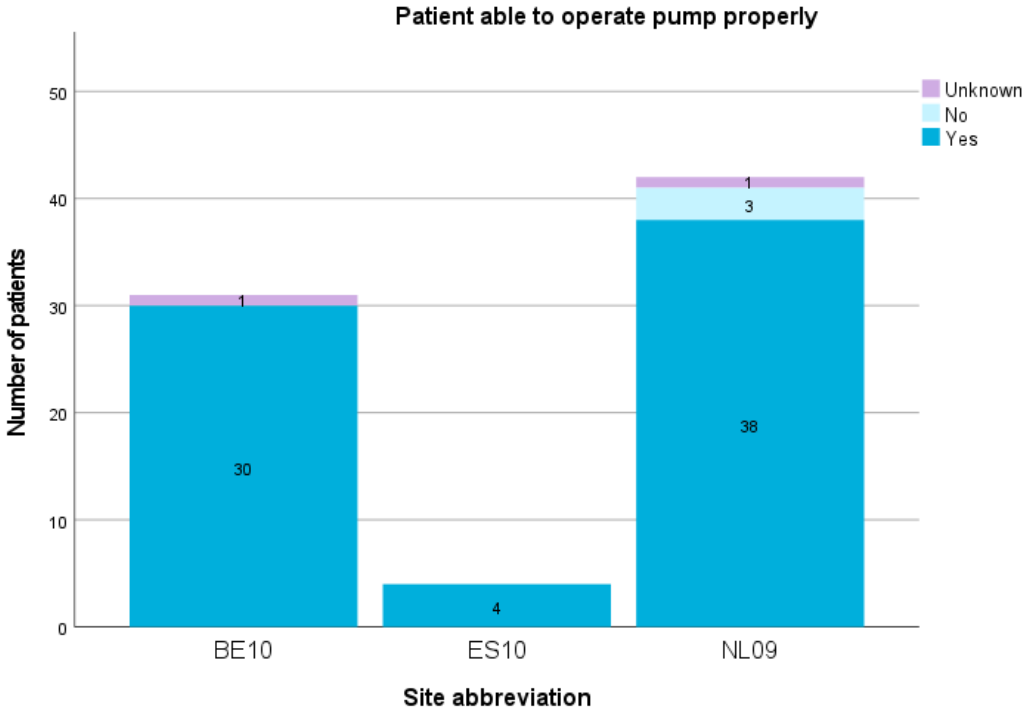
Again, most patients did not experience any complications within 3 months after the surgery, and the most reported complication was local pain at prosthesis site. There were no patients who experienced redness and swelling at the prosthesis site or fever.



Other characteristics

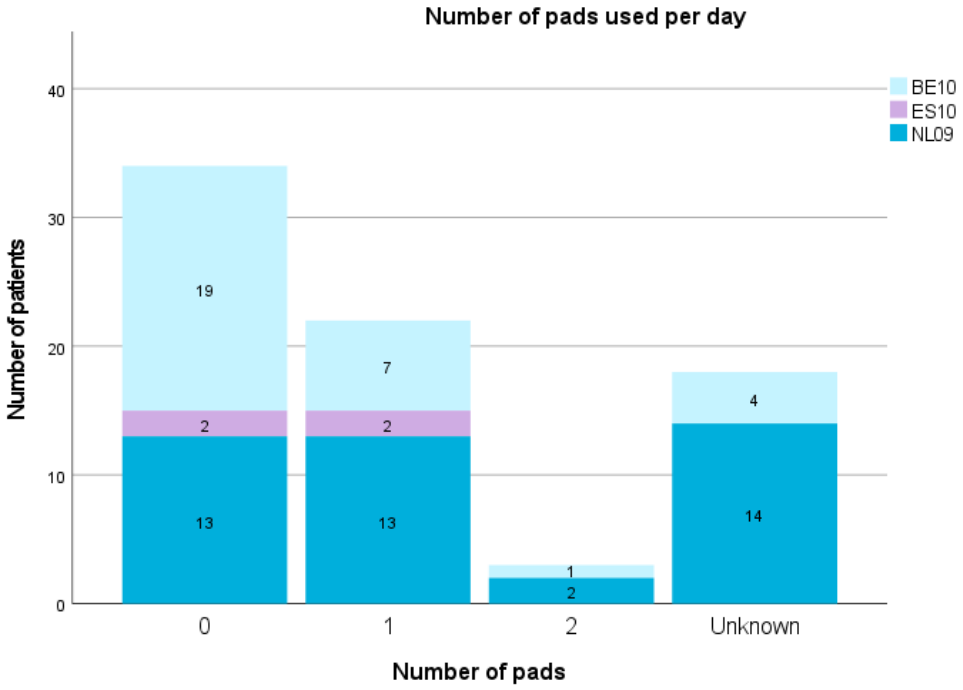
Patient can operate pump

Most patients were able to operate their pump properly.



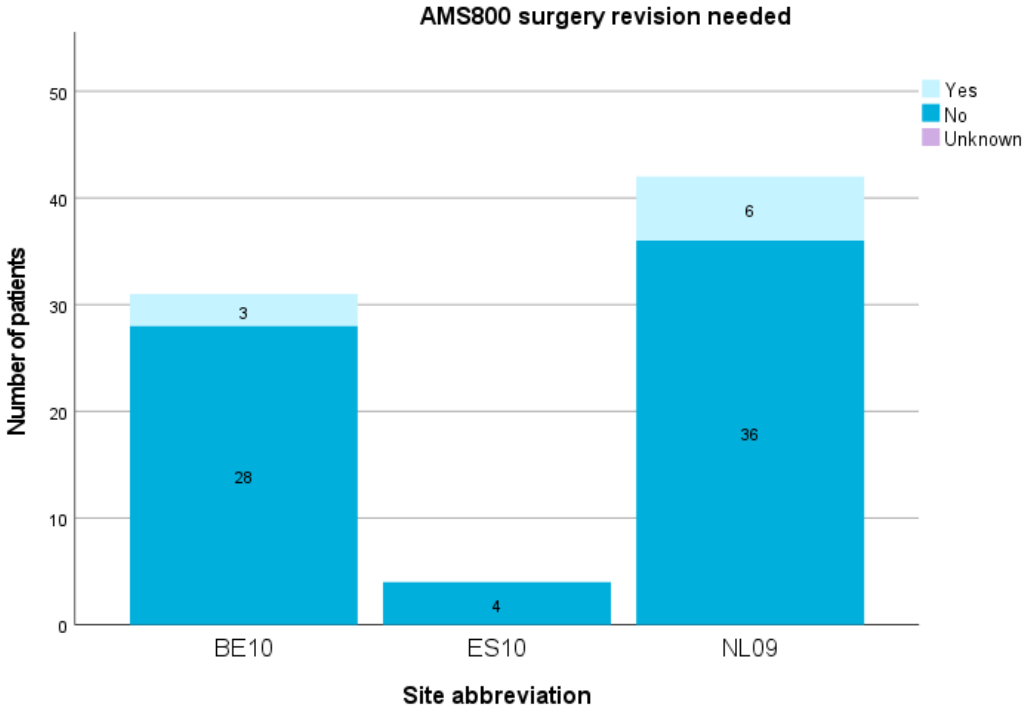
Using pads

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.



Patient had revision

No revision of the AMS800 surgery was needed for the majority of patients.



European Reference Networks

European Reference Network
for rare or low prevalence complex diseases
Network Urogenital Diseases (ERN eUROGEN)

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