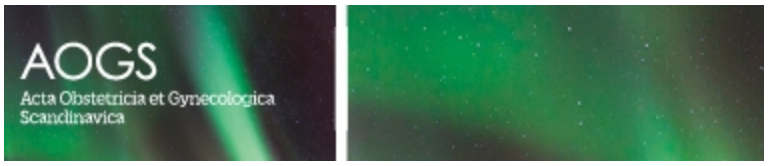

Incidence of gynecological fistula and its surgical treatment: a national registry-based study

Journal:	*Acta Obstetricia et Gynecologica Scandinavica*
Manuscript ID	AOGS-18-0892.R1
Wiley - Manuscript type:	Original Research Article
Date Submitted by the Author:	27-Feb-2019
Complete List of Authors:	Borseth, Katrine; University of Tromso, Department of Clinical Medicine Acharya, Ganesh Prasad; University of Tromso, Department of Clinical Medicine; Karolinska Institute, Department of Clinical Science, Intervention and Technology Kiserud, Torvid; University of Bergen Faculty of Medicine and Dentistry, Clinical Science; Haukeland University Hospital, Obstetrics and Gynecology Trovik, Jone; Haukeland University Hospital, Obstetrics and Gynecology; University of Bergen Faculty of Medicine and Dentistry, Clinical Science
Keywords:	Incontinence, Morbidity, Urogynaecology, Perineum

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Incidence of gynecological fistula and its surgical treatment: a national registry-based study

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Conflict of interest:

None

ABSTRACT

Introduction: Gynecological fistula (affecting female genital organs) leads to involuntary loss of urine or feces. In industrialized societies, fistulas occur mostly as complications of surgery, radiation therapy, or inflammatory bowel disease. We sought to determine the incidence of gynecological fistula and type of surgical treatment provided in Norway. **Material and methods:** This was a retrospective national cohort study of women treated for gynecological fistula (International Classification of Disease-10 code N82) during 2008-2014, identified from the mandatory Norwegian Patient Registry. To compare groups, we utilized Chi-squared or non-parametric tests. **Results**: In all, 1627 women (0.06% of the female Norwegian population) had 4475 hospital admissions with a diagnosis of gynecologic fistula. In total, 1214/1627 (75%) had fistula as the main diagnosis; 346 (29%) a urogenital fistula, 672 (55%) an enterogenital, 38 (3%) a genitocutaneous, and 22 (2%) both urinary and enteral fistula. Surgery for gynecological fistula was performed in 723 women, an incidence rate of 4.2 per 100 000 person-years (95% Confidence Interval (CI) 4.2-4.3); gynecological procedures (mostly vaginal/perineal) were performed in 163 women (23%), urological in 43 (6%), enteral in 267 (37%), and surgery involving multiple pelvic compartments in 250 (35%). Women undergoing fistula surgery had a median of three hospital contacts (95% CI 3-3), for 370 women (52%) the procedure was performed by a gynecologist, of these 212 (29%) were also operated by urologists or gastroenterologists. **Conclusions**: Gynecological fistula is rare in Norway, with an overall incidence of 6/10 000 in the female population, while the incidence of surgically treated fistula is 4.2/100 000. However, the condition represents considerable morbidity for the individual patient.

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Keywords

Fistula surgery, gynecological fistula, incidence, pelvic fistula.

Abbreviations

CI	confidence interval
ICD	International Classification of Disease
NCSP	Nordic Medico-Statistical Committee (NOMESCO) Classification of Surgical Procedures
NPR	Norwegian Patient Registry
NTCGF	National Treatment Center for Gynecologic Fistulas

Key message

Gynecological fistula is a rare condition in an industrialized setting with an incidence of 0.06% in the female population, but its management typically requires a multidisciplinary approach with gynecologists commonly involved.

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INTRODUCTION

Gynecological fistula, an abnormal passage between the female genitalia and urinary tract (*urogenital fistula*), intestine (*enterogenital fistula*) or skin (*genitocutaneous fistula*), is a debilitating condition causing discomfort in form of uncontrolled leakage of urine or feces. Obstetric trauma is still the major cause of fistula in developing countries.[1, 2] Health statistics in many countries are imprecise, but fistula incidences of up to 124 per 100 000 deliveries have been reported in developing countries, mainly caused by obstructive labor due to inadequate obstetric care.[3] Fistula as a result of birth trauma is significantly less common in industrialized countries with a reported incidence of 16.3 per 100 000 births in Norway.[4] However, surgery, radiation therapy and inflammatory bowel disease remain the main causal factors for genital fistula.[4, 5]

Genital fistula is often difficult to diagnose and treat, and may require a multidisciplinary approach as well as repeated surgical interventions. Early and prolonged drainage, either catheter drainage or enterostomy, may suffice for urogenital or enterogenital fistulas to heal, but surgical fistula closure is the dominant treatment option. Urogenital fistulas may be treated by urologists commonly using an abdominal approach, while gynecologists use a vaginal technique. Gastroenterologic surgeons may treat enterogenital fistulas using an abdominal approach for high fistulas and rectovaginal or perineal fistulas by a rectal procedure, while gynecologists prefer vaginal fistula procedures.

With the aim of creating a high-volume center for gynecological fistula treatment, the Department of Gynecology and Obstetrics at Haukeland University Hospital in Bergen was appointed the Norwegian National Treatment Center for Gynecologic Fistulas (NTCGF). Incidence and outcomes of obstetrical fistulas treated at NTCGF have previously been published.[4] A study of a 10-year cohort of women treated for gynecological fistula at this department during 1995-2005 identified surgery and not obstetric trauma as the dominant cause.[11] However, information regarding the extent of gynecological fistula and accompanying surgical treatments on a national level is lacking.

Thus, the primary objective of this study was to determine the national incidence of gynecological fistulas in Norway. The secondary aim was to determine the types of surgical

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treatments provided to these women and in which setting (type of department) this treatment was given.

MATERIAL AND METHODS

This was a retrospective national cohort study of all women diagnosed with a gynecological fistula in Norway during the seven-year period from 01.01.2008 until 31.12.2014. The data were obtained from the mandatory Norwegian Patient Registry (NPR), where all health institutions have, since 2008, been required to report diagnosis and any surgical procedure given for all their patients treated either as inpatients or outpatients, each time registered as one 'contact' in the registry.

Inclusion criteria were either the International Classification of Disease-10 (ICD-10) diagnosis N82 (gynecological fistula) of any subcategories, or the specific fistula code for surgical procedures: LEE 20 (closing of urovaginal fistula) or LEE 30 (closing of enterovaginal fistula) according to the Nordic Medico-Statistical Committee (NOMESCO) Classification of Surgical Procedures (NCSP).[12]

Gynecological fistulas were categorized as urogenital (N82.0 vesicovaginal and N82.1 other urogenital fistula) or enterogenital (N82.2 intestinovaginal, N82.3 colovaginal, N82.4 uterointestinal). Diagnosis N82.5 genitocutaneous fistula most often includes vaginoperineal fistula, and has therefore been classified as enterogenital fistula if used as a binary category (urogenital vs enterogenital fistula). If a patient had an unspecified fistula diagnosis (N82.8 other genital fistula or N82.9 unspecified) or had several different fistula diagnoses from different compartments, the fistula was classified as urogenital or enterogenital according to any corresponding organ-related surgical procedure.

The accompanying surgical codes were classified as fistula surgery if related to the same compartment as the corresponding fistula diagnosis, and categorized as enterologic fistula surgery (such as enterostomy with a diagnosis of enterogenital fistula), urologic fistula surgery (such as ureteric stent or reinplantation with a diagnosis of urogenital fistula) or specific gynecologic fistula surgery (NCSP-codes LEE procedures: notably LEE 20 closure of urovaginal fistula and LEE 30 closure of intestinovaginal fistula, or vulvo-vaginal procedures LEW, LFE or LFW with any fistula diagnosis). For unspecified fistula diagnoses, surgery related to pelvic

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organs was considered valid. Merely diagnostic procedures such as cystoscopy, rectoscopy or gynecological examination under general anesthesia were not classified as fistula surgery.

Data regarding the number of women living in Norway during 2008-2014 were collected from the official population statistics (Statistics Norway).[13] For the estimation of incidences during the entire seven-year period, the number of female inhabitants registered per 2014 was used as a denominator, while the incidence rate of gynecological fistula surgery per 100 000 person-years was based on the mean female population during the entire period.

Statistical analyses

The incidence of gynecological fistulas in Norway was calculated with a 95% confidence interval (CI). Normality of data distribution were tested by Kolmogorov-Smirnov and Shapiro-Wilk's tests. Categorical variables were compared by chi-squared test and continuous variables with non-parametric tests. The statistical program SPSS version 23.0 (IBM, Armonk, NY, USA) was used for statistical analyses. A *P*-value <0.05 was considered statistically significant and all tests are two-sided.

Ethical approval

The project was approved by the Regional Committee for Medical and Health Research Ethics (REK-number: 2015/893; date of approval: 07.02.2015) and by NPR (Ref. No. 15/4187). We obtained anonymized data where each patient had a unique ID-number created for this project ensuring that the patients could not be identified. Thus, the requirement of obtaining consent from individual patients was waived. The study is presented according to the STROBE guidelines.[14]

RESULTS

Incidence

A total of 1627 women were registered with a diagnosis of gynecological fistula in NPR between January 1, 2008 to December 31, 2014. The median age group was 51-60 years at the first diagnosis. These women had a total of 4475 hospital admissions related to gynecological fistula, and 1214 (75%) had fistula as the main diagnosis. Patients had from one to 67 registered hospital contacts each. On average, the patients had 2.75 hospital contacts, while the median number of contacts was one (95% CI 1 to 1).

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Out of 2 541 622 female Norwegian inhabitants per December 31, 2014,[13] 1627 women (0.06%, 95% CI 0.06 to 0.06) had been diagnosed with a gynecological fistula in NPR between 2008 and 2014. The fistula code was listed as the main diagnosis for 1214 women and 723 women were recorded as having had fistula surgery (Figure 1, Table 1). The Norwegian population has increased slightly during the study period with a mean female population of 2 459 510 during this seven-year period.[13] Based on this, an incidence rate of surgery for gynecological fistula of 4.2 per 100 000 person-years (95% CI 4.2 to 4.3) could be estimated.

Fistula category

Enterogenital fistula was the most prevalent type of fistula, with 915/1627 (56%) in the whole cohort, and in 65% of those who underwent fistula surgery (*P*-value <0.001 Chi-square test) Table 2 displays the different diagnoses for the whole cohort. Of note, N82.4, specified as entero-uterine fistula in the Norwegian version of NCSP, was recorded for 74 women, 4.5% of the total study population.

Urogenital fistula had been diagnosed in 445/1627 women (27%), the most common being vesicovaginal fistula. A diagnosis of both entero- and urogenital fistula had been entered for 30 women, approximately 2% of the cohort.

In total, 1214/1627 (75%) of this cohort had fistula as the main diagnosis; 672 (55%) had an enterogenital fistula, 346 (29%) a urogenital fistula, 38 (3%) a genitocutaneous fistula, and 22 (2%) were diagnosed as having both urinary and enteral fistula.

The group of patients with enterogenital/genitocutaneous fistulas (961/1627, 60%) had a median of two contacts (95% CI 1 to 2), which was significantly more than in those with other fistula categories who had a median of one (95% CI 1 to 1, *P*-value <0.001 Kruskal-Wallis test).

Fistula surgery

Fistula-related surgery was performed in 723/1 627 (44%) of the women, an incidence of 0.03% (95% CI 0.03 to 0.03) during the seven-year period (Table 1), and they had a median of three hospital contacts (from 1-67, 95% CI 3 to 3). A single enteral procedure was performed in 267 (37%) of the patients in this cohort. Nearly as common was surgery involving two surgical compartments (vaginorectal fistula repair (LEE30) combined with enterostomy), which was

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performed in 250 women (35% of all fistula surgeries). A gynecological procedure alone (mainly vaginal/perineal approach) was performed in 163 (23%) of the patients, while a urological procedure alone (mainly abdominal/transvesical approach) in only 43 (6%) (Table 3).

For those 723 women who had fistula surgery during this seven-year period, a total of 1656 surgical procedures had been performed: 895 gastroenterologic (abdominal/transrectal approach), 491 gynecologic (vaginal/perineal approach), and 270 urological (abdominal/transvesical approach).

For the 158 women with urological fistula, the procedures were predominantly ureter stenting (118), but also ureterostomy (44), reconstruction of ureter (27) such as reimplantation, and reconstruction of the urinary bladder (18). In all, 74 women were treated utilizing a specific vaginal fistula procedure (LEE20), while for 80 women other vaginal procedures were performed.

For the 493 women with an enterogenital fistula, the predominant gastroenterological procedure was enterostomy (218), while 126 had resection of ileum/colon, 191 rectal/anal procedures and 55 reversal of enterostomy. In total, 100 women underwent a specific vaginal fistula procedure (LEE30), while others (111) had various vaginal procedures (LEWcodes), and another 68 had vulva/perineal procedures (LFE or LFWcodes).

Time trend

Disregarding 2008 (the first year NPR was operating, 312 women with a fistula diagnosis had entered the registry), there was a steady geographic distribution of women with first time registered fistula diagnoses, with a median of 218 women diagnosed yearly (95% CI 200 to 249) and a median of 92 women with fistula surgery per year (95% CI 89 to 98).

Health regions and type of hospital department

Of the total patient group, 50% (818/1627) were reported as being treated in the South-Eastern Health region, 23% (374/1627) in the Western region, 14% (224/1627) in the Middle region and 13% (211/1627) in the Northern region (Table 1). A significantly higher proportion of fistula surgeries, 31% (223/723), were performed in the Western region, where the Norwegian Treatment Center for Gynecological fistula is located, compared with other health regions (*P*-value <0.001, Chi-square test).

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A majority of patients in this cohort of gynecological fistula had been diagnosed at a gynecology department, 41% (673/1627), but the diagnosis had been reached in collaboration with a surgical or medical department for 17% (268/1627). Similarly, a majority of surgeries had been performed either at a gynecological department, 22% (158/ 723), while 29% (212/723) had been a collaboration with other departments (Table 4).

DISCUSSION

According to our findings, gynecological fistulas are rare in Norway, with the incidence of surgery for gynecological fistula being 4.2/100 000 person-years. Enterogenital fistulas dominate (469/723, 65%). Multiple admissions were commonly required and a multidisciplinary approach was frequently chosen for management, with the majority of surgeries carried out in cooperation with gynecologists. A significantly higher proportion of the fistula surgeries were performed in the Western Health region, where the NTCGF is located.

As documented here, gynecological fistulas are rare but require considerable attention from the health care system. To optimize services for such rare and challenging conditions, there is always a discussion of centralization and volumes to achieve optimal treatment quality, patient flow and treatment outcomes. From this perspective, the present data provide valuable information for health providers and policy makers in priority settings and structuring services.

The data in this study are collected from diagnoses and procedures registered in NPR, a compulsory registry for all patient treatments performed at Norwegian health institutions. Regarding the validity of our findings, the NPR has been shown to have a very good coverage rate with a sensitivity of 96.8%, a specificity of 99.6% and positive predictive value of 79.7% for other conditions, such as stroke.[15] Assuming a similar rate of coverage and diagnostic precision for women registered with a diagnosis of gynecological fistula, our results would be valid. The most comprehensive control of data validity involves a review of the medical records of all patients registered in NPR. However, there is currently no such validation for gynecological fistula registered in NPR.

A study performed in 2006 described all woman referred to the Department of Gynecology, Haukeland University Hospital (Bergen, Norway), with suspected gynecological fistula during

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the period 1995-2005.[11] For 11% (9/82) of the patients, a fistula diagnosis was not confirmed. In line with these findings, it is possible that a proportion of the patients in the present registry study may have been incorrectly coded with a fistula diagnosis in NPR. Correspondingly, an overall incidence of 0.06% women with a gynecological fistula may be an overestimation. However, it is unlikely that women with an incorrect fistula diagnosis would additionally have a fistula surgery code. The estimated incidence rate of 4.2 per 100 000 person-years receiving fistula surgery is more likely a realistic number.

Out of the 1627 women with a diagnosis of gynaecological fistula, 904 had no accompanying surgical procedure. This could be due to a suspected fistula being refuted at a second examination, surgery being performed earlier than 2008 or after 2017, or the woman receiving treatment other than surgery, such as catheter drainage for traumatic/iatrogenic vesicovaginal fistula or anti-inflammatory medical treatment for inflammatory bowel disease.

These registry data cannot be used to determine etiology or outcome of treatment, as such information is not reported to NPR. Another limitation is the fact that we had no access to accompanying diagnoses for the patients. Although such information could have been helpful in narrowing down the possible cause of a fistula, it may not represent a complete account of the patients' history, which might be of importance to their present fistula; for instance, previous deliveries, surgery or radiation therapy. However, we do know that obstetrical fistulas are rare in Norway with an incidence of 0.016% of deliveries.[4] A Swedish national inpatient hospital registry study [16] identified an incidence rate of surgery for pelvic organ fistula of 23.8 per 100 000 person-years for women being subjected to a previous hysterectomy due to benign causes vs 6.3 for women without a hysterectomy (the unexposed group). Women with a diagnosis of cancer or inflammatory bowel disease were excluded from this study. The dominant fistula category following hysterectomy was urogenital, while for the unexposed cohort (women without a previous hysterectomy) enterogenital fistula dominated, the latter being in line with our findings.

An American study using inpatient data from NHS (National Hospital Discharge Survey, a national probability sample of short-stay, non-federal, US inpatient hospital discharges) during 1979-2006, described a declining incidence rate of lower reproductive tract fistula surgery from 7.8 to 4.8 per 100 000 during these years.[5] The latter is very similar to our finding of 4.2/100 000. In line with our study, the dominant type was enterogenital fistula, and the dominant

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surgical procedure a rectovaginal fistula repair. Approximately 3% of their patients had a concurrent diagnosis of inflammatory bowel disease and 9% were noted to have fistula as a complication of childbirth. The type of department and medical specialty treating these women was not reported in the NHS study. Their diagnoses were reported as ICD-9 codes and surgical procedures as ICD-9-CM codes, and thus do not correspond with those that we used.

In the Norwegian single-center cohort study,[11] the dominant fistula category was enterogenital (61/81, 74%) in accordance with both the present study and the US NHS study.[5] We also identified those with an enterogenital fistula as the largest group receiving surgery, with significantly more hospital contacts compared with other fistula categories. This is in line with the fact that patients with enterogenital fistulas often receive temporary enterostomy in addition to a surgical fistula repair.[8, 17]

In contrast with other registry studies[5, 16, 18] where medical specialty/type of department has not been accounted for, our study demonstrates that women with genital fistula underwent diagnostic and treatment procedures from a variety of specialists. As more than 50% of hospital contacts and surgeries were conducted at a gynecological department, the gynecologists seem to be a key resource in the multidisciplinary approach.

NPR would not release information regarding treatment at individual hospitals; thus, we could not identify patients as specifically treated at the NTCGF. However, the fact that a significantly larger proportion of patients had fistula surgery performed in the Western hospital region than in other regions corroborates the notion that NTCGF functions as a referral center for the entire country.

CONCLUSION

Gynecological fistula is rare in Norway with an overall incidence of 6/10 000 in the female population and with a surgical treatment incidence of 4.2/100 000 person-years. The repeated admissions and treatments underscore the fact that the condition represents a challenging morbidity for individual patients and the health care system.

Acknowledgements:

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This project has used data from the Norwegian Patient Register (NPR). However, the authors were solely responsible for the analysis, interpretation and presentation of the data provided.

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Table and Figure legends

Table 1. Incidence of gynecologic fistula and fistula surgery during 2008-2014, specified according to different health regions in Norway.

Table 2. Women diagnosed with gynecological fistula during 2008-2014 comparing fistula category and whether any fistula surgery[a] was performed.

Table 3. Women registered with a gynecological fistula diagnosis in NPR[a] during 2008-2014 (n=1627) categorized according to type of surgery as defined by NOMESCO Classification of Surgical Procedures.

Table 4. Type of hospital department providing treatment for 1627 woman registered with a gynecological fistula diagnosis in NPR[a] during 2008-2014.

Figure 1. Gynecologic fistula, a nation-wide hospital cohort of 1627 women entered in the Norwegian Patient Registry during 2008-2014.

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Table 1. Incidence of gynecologic fistula and fistula surgery during 2008-2014, specified according to different health regions in Norway.

	Female inhabitants in 2014 **n[a] (% of all women)**	**Women diagnosed with gynecologic fistula** **n (% of women with fistula)**	**Incidence of gynecologic fistula** **(95% CI[b])**	**Women with fistula surgery[c] performed** **n (% of women with surgery)**	**Incidence of gynecologic surgery (95% CI)**
Total in Norway	**2 541 522**	**1627**	**0.0006 (0.0006-0.0006)**	**723**	**0.0003 (0.0003-0.0003)**
South-Eastern Region	1 429 295 (56 %)	818 (50)	0.0006 (0.0006-0.0006)	346 (48)	0.0002 (0.0002-0.0002)
Western Region	529 438 (21 %)	374 (23)	0.0007 (0.0006-0.0008)	223 (31)	0.0004 (0.0003-0.0005)
Middle Region	346 947 (14 %)	224 (14)	0.0006 (0.0005-0.0007)	82 (11)	0.0002 (0.0002-0.0003)
Northern Region	235 842 (10 %)	211 (13)	0.0009 (0.0008-0.0010)	72 (10)	0.0003 (0.0002-0.0004)

[a] n= numbers, [b]CI = Confidence interval, [c]Fistula surgery: surgical codes related to the same compartment as the corresponding fistula diagnosis, (eg enterostomy with a diagnosis of enterogenital fistula)

Table 2. Women diagnosed with gynecological fistula during 2008-2014 comparing fistula category and whether any fistula surgery[a] was performed.

Category of gynecological fistula	**International Classification of Diseases version 10 diagnosis (n[b])**	**Women with fistula surgery n(%)**	**Women without fistula surgery n (%)**
Urogenital	N82.0 vesicovaginal (264) N82.1 other urogenital (181)	158 (22)	287 (32)
Enterogenital	N82.2 intestinovaginal (144) N82.3 colovaginal (697) N82.4 intestinouterine (74)	469 (65)	446 (49)
Genitocutaneous	N82.5 genitocutanous (46)	24 (3)	22 (2)
Unspecified[c]	N 82.8 other genital (65) N82.9 unspecified (126)	52 (7)	139 (15)
Uro- and enterogenital	Several fistula types (10)	20 (3)	10 (1)

[a]Surgery related to the same compartment as the corresponding fistula diagnosis,
[b]n=numbers, [c]Surgery related to pelvic organs would be considered valid

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Table 3. Women registered with a gynecological fistula diagnosis in NPR[a] during 2008-2014 (n=1627) categorized according to type of surgery as defined by NOMESCO Classification of Surgical Procedures.

Procedure	All patients n[b] (%)	Fistula as main diagnosis n (%)	Fistula related surgery[c] n (%)
Gynecological fistula surgery[d]	163 (10)	146 (12)	163 (23)
Enterological fistula surgery[e]	267 (16)	184 (15)	267 (37)
Urological fistula surgery[f]	43 (3)	28 (2)	43 (6)
Several types of fistula surgery[g]	250 (15)	199 (16)	250 (35)
Only diagnostic procedures[h]	152 (9)	117 (10)	0
Surgical procedures unrelated to fistula[i]	173 (11)	117 (10)	0
No surgical procedures	579 (36)	423 (35)	0
Total	1627	1214	723

[a]NPR: Norwegian (National) Patient Registry, [b]n=number, [c]Surgery related to the same compartment as the corresponding fistula diagnosis, [d]Either a LEE code (specific fistula closure) or a surgical code related to uterus/vagina/vulva, mainly LEW, LFE or LFW, [e]Surgery within the JF (ileal/colon), JG (rectal) or JH(anal/perianal) categories, [f]Surgery within the KB (ureter), KC (urinary bladder) or KD (urethra) categories, [g]Multiple procedures relating to different pelvic compartments, [h]Cystoscopy, rectoscopy or gynecological examination under general anesthesia, [i]Surgical procedures unrelated to the corresponding pelvic organ/compartment

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Table 4. Type of hospital department providing treatment for 1627 woman registered with a gynecological fistula diagnosis in NPR[a] during 2008-2014.

Department	**All patients n[b] (%)**	**Fistula as main diagnosis n (%)**	**Fistula related surgery n (%)**
Gynecological department only	673 (41)	531 (44)	158 (22)
Surgical (general, gastric or urologic surgical department) only	499 (31)	342 (28)	275 (38)
Medical department only	89 (6)	29 (2)	12 (2)
Several departments including gynecological (gynecological and surgical or medical department)	268 (17)	241 (20)	212 (29)
Surgical and medical department	98 (6)	71 (6)	66 (9)
Total	1627	1214	723

[a]NPR: Norwegian (National) Patient Registry, [b]n=number

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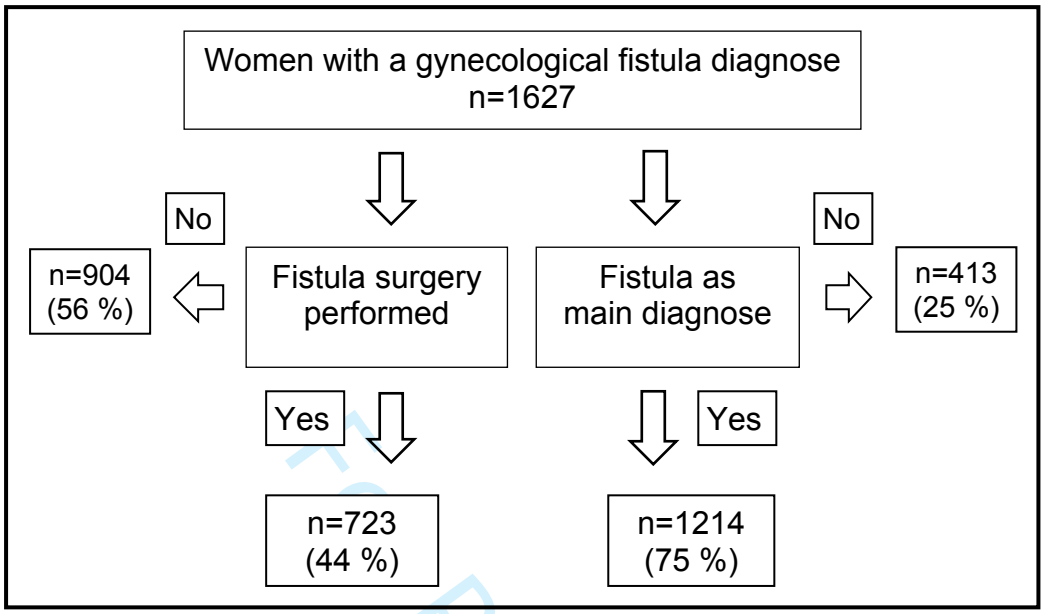
Figure 1. Gynecological fistula, a nation-wide hospital cohort of 1627 women entered in the Norwegian Patient Registry during 2008-2014.



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