

Gynaecological Prolapse Surgery in Very Old Female Patients

A Case-Control Study on Co-Morbidity and Surgical Complications

Gynäkologische Deszensuschirurgie bei hochaltrigen Patientinnen

Eine Fallkontrollstudie zu Komorbidität und chirurgischen Komplikationen

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Key words

- very elderly people
- prolapse surgery
- co-morbidity
- surgical complications
- Clavien-Dindo classification system

Schlüsselwörter

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- Komorbidität
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- Clavien-Dindo-Klassifikationssystem



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Abstract

Background: The aim of this study is to compare very elderly female patients with a younger control group after prolapse surgery with regard to co-morbidity and complications.

Method: In a case-control design, the consecutive data of patients after prolapse surgery at the age of over 80 years and those of a control group were analysed by means of the Clavien-Dindo (CD) classification of surgical complications, the Charlson Comorbidity Index and the Cumulative Illness Rating Scale Geriatrics (CIRS-G). Statistics: Student's t, Fisher's exact and Mann-Whitney U tests.

Results: The analysis comprised n = 57 vs. n = 60 operations. In the very elderly patients there was often a grade IV prolapse (p < 0.001), apical fixations were more frequent (p < 0.001), but the operating times were not different. In the very elderly patients 21% CD II+III complications were observed, in the control group 6.6% (p = 0.031). No CD IV and V complications occurred in either group, the duration of inpatient stay amounted to 5 (± 1) vs. 4.1 (± 0.8; p < 0.001) days, the very elderly patients needed an inpatient follow-up more frequently (p < 0.001). The co-morbidities of the very elderly patients differed from those of the control group in number (median 2.0 vs. 1.5; p < 0.001), in CIRS-G (4.1 ± 2.2 vs. 2.4 ± 1.7; p < 0.01) and in Charlson Index (1.6 ± 1.6 vs. 0.5 ± 0.7; p < 0.001).

Conclusions: A prolapse in very elderly women can be safely managed by surgery. In no case did the complications require intensive care treatment nor were they life-threatening, but they did lead to a longer duration of hospital stay and more frequently to further treatment geriatric or inpatient internal medicine facilities.

Zusammenfassung

Hintergrund: Ziel ist der Vergleich von hochaltrigen Patientinnen mit einer jüngeren Kontrollgruppe nach Deszensuschirurgie hinsichtlich Komorbidität und Komplikationen.

Methode: Im Fallkontrolldesign erfolgte die Analyse konsekutiver Daten nach Deszensuschirurgie ab 80. Lebensjahr und einer Kontrollgruppe mittels Clavien-Dindo-(CD-)Klassifikation chirurgischer Komplikationen, Charlson Comorbidity Index und Cumulative Illness Rating Scale Geriatrics (CIRS-G). Statistik: Student's t-, Fisher's Exact- und Mann-Whitney U-Tests.

Ergebnisse: Es wurden n = 57 vs. n = 60 Operationen erfasst. Bei Hochaltrigen lag häufiger ein Grad-IV-Prolaps vor (p < 0,001), es erfolgte häufiger eine apikale Fixation (p < 0,001), die OP-Zeiten unterschieden sich nicht. Bei Hochaltrigen fanden sich 21% CD-II+III-Komplikationen, in der Kontrollgruppe 6,6% (p = 0,031). In beiden Gruppen traten keine CD-IV- und -V-Komplikationen auf, die Verweildauer lag bei 5 (± 1) vs. 4,1 (± 0,8; p < 0,001) Tagen, eine stationäre Weiterbetreuung erfolgte häufiger bei hochaltrigen Patientinnen (p < 0,001). Die Komorbidität Hochaltriger unterschied sich von der Kontrollgruppe in der Anzahl (median 2,0 vs. 1,5; p < 0,001), im CIRS-G (4,1 ± 2,2 vs. 2,4 ± 1,7; p < 0,001) und im Charlson-Index (1,6 ± 1,6 vs. 0,5 ± 0,7; p < 0,001).

Schlussfolgerungen: Ein Deszensus kann bei hochaltrigen Patientinnen sicher chirurgisch versorgt werden. Komplikationen erreichten in keinem Fall Intensivtherapiepflichtigkeit oder Lebensbedrohlichkeit, führten aber zu einer verlängerten Verweildauer und häufiger zu geriatrischer oder internistischer stationärer Weiterbehandlung.

Introduction

According to the Federal Statistical Office every second woman in Germany will reach the age of 85 years [1]. The population in Germany is not only becoming older but also more healthy and active in old age. Since genital prolapse is a problem affecting elderly women [2, 3], clinicians in pelvic floor centres are increasingly facing the complex questions of if and with what risks also the very elderly patients who often have co-morbidities can be recommended to undergo surgical treatment. The objectives in these cases are to improve the quality of life and to maintain social independence. The decision to subject a woman aged 80 or more years to prolapse surgery should be made in dependence on the level of suffering, the lack of alternatives, e.g., pessary therapy in cases with eroded or ulcerated vaginal skin [4], on the general condition and the presence of co-morbidities. The choice or operative method [5] with its impact on the duration of surgery should be adapted individually to the complex situation. Occlusive methods should be offered in a comprehensive consultation, if necessary in the presence of a close relative of the patient such as her partner, children or authorised caregiver.

The aim of this retrospective case-control study is to compare the disease courses after surgical prolapse surgery between very elderly patients and a younger control group with a special emphasis on co-morbidities and registration of surgical complications in the postoperative period.

For this purpose we employed a standardised, validated registration system, such as the classification of surgical complications according to Clavien-Dindo [6], which is used on large patient collectives in analyses of patient safety in surgical specialties such as gynaecology [7, 8], abdominal surgery [6] or urology [9] and is recommended in the guidelines of professional societies [9]. The standardised registration of comorbidities was carried out using the Charlson Comorbidity Index [10] and the Cumulative Illness Rating Scale Geriatrics [11, 12], that were evaluated by de Groot et al. [13] after an analysis of 13 different methods for recording co-morbidities as valid and reliable instruments for use in clinical research [13].

A central point of our study were the questions do the very elderly patients operated in our centre differ from a younger control group with regard to pre-existing co-morbidities and surgical complications and whether genital prolapse in the very elderly female patient can safely be managed surgically.

Patients and Methods

Study design and identification of the patient cohort

In a case-control design the consecutive data of elderly patients more than 80 years old who were operated at the University of Jena Gynaecology Department for prolapse correction between 2009 and 2015 were analysed retrospectively. The patients in the control group were assigned on the basis of an average age of 63 ± 10 (standard deviation [SD]) from our hospital's cohort of patients after pelvic floor surgery [14]. All consecutively registered patients of the control group underwent a prolapse correction in the university hospital in 2015. Data acquisition was based on electronic or written patient records of case history, operation report, course, discharge letter, and outpatient records.

Recorded variables

We systematically recorded patient characteristics (age, body mass index [BMI], prolapse grade, status after hysterectomy), the type and number of co morbidities in the case history, such as, e.g., status after stroke, arthrosis, eye diseases, COPD/asthma, dementia, depression, diabetes mellitus, cardiac insufficiency, chronic ischaemic heart disease, status after pacemaker implantation, total hip/knee joint replacement, hypertension, liver cirrhosis, status after pulmonary embolism, status after myocardial infarction, renal insufficiency, osteoporosis, thyroid disease, hearing impairments and status after thrombosis as well as peri-operative factors such as operation time, duration of hospital stay and surgical complications.

Definitions and registration system

Multi-morbidities were defined according to van den Akker as "the coexistence of two or more diseases in one person" [15]. They were recorded retrospectively on the basis of patient records using the Charlson Comorbidity Index [10] and Cumulative Illness Rating Scale Geriatrics (CIRS-G) [11, 12] in the diagnosis sheets provided for this purpose [10–14]. A surgical complication was defined as "each and any deviation from the ideal postoperative course which is not inherent to the procedure and excludes failure of the therapy" [17] and systematically classified according to the valid system of Clavien and Dindo (CD) which is recommended by the professional societies [9] and very frequently used in surgical medicine [6, 8, 14, 18–20]. The observation time encompassed the postoperative inpatient stay and a 48-h readmission interval.

Statistical analysis

The data analysis was done with SPSS (Statistical Package for the Social Sciences software, Version 15.0; SPSS Inc., Chicago, IL, USA) and the statistics with Student's t, Fisher's exact and Mann-Whitney U tests.

Results

Characteristics of the study cohort

In the time period in question $n = 57$ operations with the aim of prolapse correction were performed in elderly patients over the age of 80 years and $n = 60$ operations on patients aged between 53 and 73 years according to the definition and inclusion criteria for the control group. Since in $n = 3$ cases in the group of very elderly patients and in one case in the control group within the given time period were operations for recurrences, altogether the data for $n = 54$ vs. $n = 59$ patients could be included in the analysis. The patient characteristics age, BMI and prolapse stage [21] as well as the presence of a status after hysterectomy are presented in **Table 1**.

Surgical techniques

Surgical techniques used in the group of very elderly patients vs. those of the control group were in $n = 40/57$ (70.2%) vs. $n = 48/60$ (81.7%; $p = 0.001$) cases a lateral or central defect closure with autologous tissue in the anterior compartment by means of an anterior colporrhaphy and in $n = 12/57$ (20.0%) vs. $n = 11/60$ (18.3%; $p = 0.817$) with a vaginal mesh. In $n = 25/57$ (43.8%) vs. $n = 54/60$ (90%; $p = 0.049$) cases the defect closure was performed in the posterior compartment by means of a posterior colporrhaphy and in $n = 25/57$ (43.8%) vs. $n = 6/60$ (10%; $p = 0.001$) a correction

Table 1 Patient characteristics of the very elderly patients and those of the control group with statistical differences.

Variable	Very elderly n = 54	Control n = 59	p
Age (year)	84.2 ± 3.3	64.7 ± 6.3	<0.001*
BMI (kg/m ²)	27.4 ± 4.2	28.3 ± 5.3	0.304*
Obesity (BMI ≥ 30)	22.2%	38.9%	0.073**
Status after HE	59.6%	52.5%	0.352**
Prolapse grade IV***	56.1%	25%	<0.001**

* Student's t tests, ** Fisher's exact tests, *** International Continence Society
BMI: body mass index, HE: hysterectomy

in level I [22] was performed by means of a sacrospinal fixation (n = 21 vs. n = 6; p = 0.001) or laparoscopic sacropexy (n = 4). In n = 4 patients of the very elderly group, a colpcleisis was performed whereas for the younger patients in the control group no such occlusive procedure was considered.

In n = 18/57 (31.6%) vs. n = 29/60 (48.3%; p = 0.089) cases a laparoscopically assisted vaginal hysterectomy was performed within framework of the surgical prolapse correction whereas in n = 4/57 (7%) vs. n = 2/60 (3.3%; p = 0.431) of the cases the uterus was left in place (Table 2).

Peri- and postoperative data and analysis of complications

The average operating time for all interventions in the group of very elderly patients versus those in the control group amounted to 93.2 (SD 65.4) vs. 87.9 (SD 48.0; p = 0.660) minutes, the average postoperative duration of hospital stay to 5 (SD 1) vs. 4.1 (SD 0.8; p < 0.001) days. In the group of very elderly patients there were nine postoperative referrals to a geriatric hospital, two patients were transferred to the cardiology department at the end of the postoperative inpatient treatment and two patients were admitted to a senior citizens and nursing home for social reasons. In the control group all patients were sent home from the gynaecological department.

Intra-operative complications such as bleeding requiring blood transfusion or injury to a neighbouring organ did not occur in either group. In the group of very elderly patients four symptomatic urinary tract infections (4/57; 7%) were observed in the postoperative inpatient period, that were treated with antibiotics as well as two bladder voiding disorders (2/57; 3.5%) that received drug treatment with distigmine (Ubretid®). These were classified as CD II complications requiring drug treatment (Table 3). Other complications typical for prolapse surgery such as haematomas or abscesses in the region of the operation site, revisions in cases of suture dehiscences or after-bleeding, and secondary management with a suprapubic urinary diversion in cases of therapy-refractory voiding disorders were also not observed. Further complications requiring therapy in the postoperative interval were n = 2/57 non-ST-elevation myocardial infarctions (NSTEMI) with further management in the cardiology department and a case of hallucinations requiring drug treatment. Both were classified as CD II. An elbow fracture due to a fall was assigned as a CD IIIb complication (Table 3).

In the control group there was one superficial haematoma that did not require further treatment (CD I). The CD II complications were assigned as one symptomatic urinary tract infection, one

Table 2 Surgical techniques, operating time, inpatient hospital stay and inpatient medical further management of the very elderly patients and those in the control group with statistical differences.

Variable	Very elderly n = 57	Control n = 60	p
Anterior colporrhaphy	70.2%	81.7%	0.001**
Anterior vaginal mesh	20.0%	18.3%	0.817**
Posterior colporrhaphy	43.8%	90.0%	0.049**
Sacrospinal fixation	36.8%	10.0%	0.001**
Lsc/sacropexy	7.0%	0.0%	0.053**
LAVH	31.6%	48.3%	0.089**
Retention of uterus	7.7%	3.3%	0.431**
Colpcleisis	7.0%	0.0%	0.053**
OP time (minutes)	93.2 ± 65.4	87.9 ± 48.0	0.660*
Duration of hospital stay (d)	5.0 ± 1.0	4.1 ± 0.8	<0.001*
Inpatient further medical management	19.3%	0%	<0.001**

* Student's t tests, ** Fisher's exact tests

Lsc: laparoscopy, LAVH: laparoscopically assisted vaginal hysterectomy

Table 3 Number of co-morbidities with special emphasis on joint replacements of the lower limbs and dementias, CIRS-G and Charlson Index scores for the very elderly patients and those in the control group with statistical differences. Surgical complications according to CD [6]. No CD IVa, IVb or V complications were recorded.

Variable	Very elderly n = 57	Control n = 60	p
Co-morbidities			
▶ n = 0	1.8%	1.6%	
▶ n = 1	20.4%	32.2%	
▶ n = 2	35.2%	23.7%	
▶ n = 3	9.3%	23.7%	
▶ n = 4	13.0%	3.4%	
▶ n ≥ 5	24.6%	0.0%	
Average value	2.0	1.5	<0.001*
CIRS-G (MV ± SD)	4.1 ± 2.2	2.4 ± 1.7	<0.001**
Charlson Index (MV ± SD)	1.6 ± 1.6	0.5 ± 0.7	<0.001**
Total hip/knee replacement	29.6%	10.1%	0.016***
Dementia	9.2%	0.0%	0.023***
Clavien-Dindo (CD)			
▶ CD I	0%	1.6%	1.0***
▶ CD II	17.5%	6.6%	0.09***
▶ CD III a	0%	0%	1.0***
▶ CD III b	3.5%	0%	0.235***
▶ CD II + III	21.0%	6.6%	0.031***

* Mann-Whitney U tests, ** Student's t tests, *** Fisher's exact tests

CIRS-G: Cumulative Illness Rating Scale Geriatric [11, 12], MV: mean value, SD: standard deviation

erysipelas, one manic-depressive illness with medicinal management and one mild anaemia treated with an iron formulation (Table 3). Other complications typical for prolapse surgery such as haematomas or abscesses in the region of the operation site, revisions in cases of suture dehiscences or after-bleeding, secondary management with a suprapubic urinary diversion in cases of therapy-refractory voiding disorders were also not observed in these groups.

The overall morbidity with regard to complications requiring therapy (CD II+III) amounted to 21% in the group of very elderly patients vs. 6.6% in the control group ($p=0.031$). There were no complications requiring intensive care therapy in either group.

Co-morbidity analysis

The number of co-morbidities in both groups, calculation of mean values ($p < 0.001$), determination of CIRS-G ($p < 0.001$) and Charlson Index ($p < 0.001$) as well as the frequency of occurrence of total hip/knee joint replacements ($p=0.016$) and dementias ($p=0.023$) in the respective groups are presented in **Table 3**.

Discussion

The present contribution shows that genital prolapse in very elderly patients aged over 80 years can be safely managed surgically by means of reconstructive or occlusive methods. In this patient group a uterovaginal total prolapse [21] was observed more frequently than in the younger control group. Also, co-morbidities and surgical complications were more frequent in the elderly patients in comparison to the control group. In no case were they life-threatening or led to the need for intensive care but often resulted in a prolonged inpatient stay and to frequent referrals for further treatment to a geriatric or internal medicine department.

The analysis of the patient characteristics showed that a status after hysterectomy was equally present in both groups whereas for obesity there was a trend towards a lower frequency in the over 80 year olds. However, no patient had a BMI of less than 20 kg/m², which in the sense of malnutrition [23] for geriatric patients could be associated with a higher post-operative morbidity, e.g., through wound infection or falls.

In the control group of younger patients a situation-adapted reconstruction of pelvic floor compartment defects was undertaken more often, while the level I in the apical compartment had to be reconstructed more frequently in the group of very elderly patients. This reflects the higher number of genital total prolapses in the group of the over 80 year olds. Vaginal alloplastic implants were used equally often in both groups. Also there were no differences between the groups with regard to the decision between hysterectomy and retention of the organ. The vaginal occlusive method of colpocleisis was exclusively carried out in the very elderly patients. On account of the low number of cases, a subgroup analysis was not possible here. Data from the literature support the assumption that a colpocleisis leads to a lower rate of complications among the elderly patients than the reconstructive pelvic floor surgery due to the reduced duration of the operation [24]. Referred to the collectives, there was no difference in the operating time which may be attributed to the fact that although patients with a high degree (total) prolapse were found among the over 80 year olds, methods with shorter operating times such as, e.g., colpocleisis, were preferred in this group. The less pronounced pathologies of the control group were rather managed using situation-adapted compartment reconstructions.

The figures for both groups show on average a duration of hospital stay lower than the number of days defined by the German DRG system. The average duration of hospital stay after prolapse operations depending on the method amounts to between 5.6 (without hysterectomy) and 6.1 days (with hysterectomy) [25]. As expected, the postoperative convalescence for the very elderly patients required a longer inpatient stay in our surgical unit, this

can be deduced from the analysis of co-morbidities as well as that of the surgical complications [26] and may possibly also have a social component. The discharge into further medical care facilities such as a geriatric or cardiology hospital/department as was seen exclusively for the very elderly patients can also be explained in this way [26]. In a retrospective analysis of 283 patients aged 76 or more years, Stepp et al. found 5.2% intra-operative and 24% post-operative complications but a standardised recording system, e.g., such as that according to Clavien and Dindo, was not used [27]. This makes a comparison of the data difficult. In our study we found in the group of over 80 year olds an overall morbidity according to CD of 21%. The post-operative morbidity was higher than that in the younger control group as shown by the comparison of complications of the groups CD II and CD III requiring treatment. This corresponds to the observations of other groups [24,28]. In a large retrospective cohort study with over 250 000 patients Sung et al. found a 1.4-fold elevated risk for peri-operative complications in patients aged 80 years or more [24] on comparison with younger patients. The mortality risk was increased 13.6-fold for patients in this age group [24]. In our study there were no patients requiring intensive care medicine (CD IVa and IVb) in either group and also no deaths (CD V). Frequent postoperative complications among the elderly patients could be falls, delirium, wound infections and cardiological diagnoses [26]. In our study groups these were found as isolated cases and exclusively in the group of over 80 year old patients. No wound infections with problem-causing pathogens were observed in our examined cohorts.

Although it is known that advanced age represents an independent risk factor for surgical complications [26], age alone should not be a contraindication for surgical therapy [26,28]. It has been observed in clinical trials that the type and number of co-morbidities determine the risk for surgical complications in elderly female patients. The co-morbidity index used by Sung et al. shows for each unit a four-fold increased risk of complications [24]. The analysis of co-morbidities in our study by means of the median test and two validated methods (CIRS-G [11, 12, 16] and Charlson-Index [10]) shows that for patients over the age of 80 years in comparison with the younger control group not only the median value of the number of co-morbidities but also the average values of the CIRS-G analysis [11, 12, 16] and the Charlson-Index [10] are higher. Both indices are considered in clinical health-care research and geriatrics to be the best validated and most suitable methods to represent co-morbidity status in scientific analyses [13]. An advantage of CIRS-G is the registration of morbidities in defined organ systems [11, 12, 16]. Depending on the inclusion criteria, this score among geriatric patients lies between 19.7 [23], 5.5 [29] and 2.4 [30], whereby the CIRS-G in studies such as ours on elective surgery in very elderly patients is seen to be in the lower range [30]. The comparatively low CIRS-G score of 4.07 in our study shows that the elderly patients who underwent pelvic floor surgery in our department had relatively good general conditions and following their entitlement to an appropriate quality of life chose to undergo elective urogynaecological surgery. The Charlson Index [10], in turn, does not appear to be sufficiently extensive in the registration of variables for an analysis of pelvic floor patients [27], even though it was used in a similar analysis involving a group comparison between over 65 year old and under 65 year old pelvic floor patients [27, 31]. Knowledge of co-morbidities of the musculoskeletal system is relevant for the gynaecological surgeon because the vaginal approach necessitates a lithotomy positioning of the patient [5]. For

this reason we compared the presence of total hip and knee joint replacements separately. These co-morbidities were seen more often in the group of very elderly patients but no associated consequences of the positioning were found in the complication analysis. Since it appears to be significant for the care costs in a non-psychiatric surgical department like ours and is known to increase the risk for post-operative hallucinations [5], we have recorded the diagnosis “dementia” separately. It was seen more often in the group of very elderly patients.

Over 80-year-old patients who have to undergo pelvic floor surgery are already a preselected patient collective. Pelvic floor specialists need to balance therapeutic options with the patients' general condition and the anaesthesiologists need to evaluate their ability to endure narcosis. In these cases especially the functional status, besides age of the patient, should be considered as surrogate parameters for a postoperative risk [26]. The result of our analysis allows the conclusion that the involved specialist groups have undertaken a responsible risk-benefit analysis. The implementation of preoperative cognitive and functional assessments [26,32] together with a standardised registration of co-morbidities [31,33] in the very elderly pelvic floor patients with participation of anaesthesiologists, geriatric specialists and internists could be the way to accurately inform the patients and their relatives with regard to the choice between reconstructive or occlusive methods and about the risks of surgical complications. The character of a monocentric case-control study implements a bias in the retrospective nature within the framework of data acquisition from possibly inhomogeneous documentation. The low case number of occlusive methods does not allow a comparison of this technique with the data after reconstructive pelvic floor surgery. The low number of complications as target variable does not allow for binary or multivariate regression analyses in order to demonstrate cause-effect relationships of variables such as operating time, surgical methods, BMI or co-morbidity. A prospective preoperative, standardised registration of these parameters in pelvic floor patients should in future studies be correlated with the prospective and standardised records of post-operative complications, in order to establish for the patient clarification a viable predictor for risk estimation.

Conclusions for the Practice

The increasing number of very elderly patients with co-morbidities but also their rights for independence and quality of life confront urogynaecologists more and more with the complex task of providing low-risk treatment of pelvic floor defects in female patients aged 80 or more years. Very elderly patients more and more often present with a total uterovaginal prolapse that could safely be managed by surgery using reconstructive or occlusive methods. Among the over 80 year olds there are comparatively more co-morbidities and surgical complications of the classes CD II and III. In no case did the need for intensive care medicine occur or a life-threatening situation arise. Among the very elderly patients there was a need for a longer inpatient stay and often for further inpatient care in a geriatric or internal medical unit.

Contributions of the Authors

A.R. Mothes: Idea, protocol/project development, data acquisition and management, preparation of the manuscript

T. Lehmann: Data management, statistics

A. Kwetkat: Project development, manuscript revision

M.P. Radosa: Project development, manuscript revision

I.B. Runnebaum: Project development, manuscript revision

Conflict of Interest

None.

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