Abstract

Objective: to test the hypothesis that PROMPT reduces permanent brachial plexus palsy and perinatal tears. Design: prospective / retrospective cohort study. Setting: Hanover Medical School, Germany. Population / Sample: a self-selected population. Methods: training period November 9th 2017 until 31st December 2019, control January 1st 2004 until November 8th 2017. Main outcome measures: shoulder dystocia, non-permanent and permanent brachial plexus injuries (BPI), perineal tears III°/IV°, manual manoeuvres, and asphyxia. Results: there was a total of 22,640 births, shoulder dystocia increased from 48/18,031 (0.27%) to 23/4,609 (0.50%) (p=0.017), OR 1.88, 95%-CI [1.14; 3.09] whereas BPIs decreased from 7/48 (14.6%) to 1/23 (4.3%) (p=0.261). There was 1/7 (14.2%) of permanent BPI before and 0/1 (0%) case after. Perinatal asphyxia increased from 3/48 (6.3%) to 4/23 (17.4%) (p=0.23). However, adverse outcomes after one year were zero. McRoberts\textsuperscript{\textregistered} increased from 37/48 (77.1%) to 23/23 (100%) (p=0.013), OR 1.62, 95%-CI [1.33; 1.98] and internal rotation manoeuvres and manual extraction of the posterior arm from 6/48 (12.5%) to 5/23 (21.7%) (p=0.319). Episiotomies decreased from 5,267/18,031 (29.2%) to 836/4,609 (18.1%) (p<0.001) OR 0.54, 95 %-CI [0.49, 0.58], whereas perineal tears III°/IV° associated with shoulder dystocia increased from 1/48 (2.1%) to 1/23 (4.8%), (p=0.546). Vaginal operative deliveries remained constant (6.5% vs 7%). Conclusions: PROMPT significantly improves the management of shoulder dystocia and decreases permanent brachial plexus injuries, but not perinatal tears III°/IV°.
ABSTRACT

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Conclusions: PROMPT significantly improves the management of shoulder dystocia and decreases permanent brachial plexus injuries, but not perinatal tears III°/IV°.

Funding: there was no funding.

Keywords: PROMPT, shoulder dystocia, brachial plexus injury, asphyxia, perineal tear, McRoberts Manoeuvre, internal rotation, arm extraction, episiotomy.

FUNDING

No external funding was requested for this study. Spyridon Papageorgiou covered the expenses for statistical analysis.

INTRODUCTION

PROMPT (PRactical Obstetric MultiProfessional Training) is a trial-based multi-professional training concept of rare obstetric complications focusing on teamwork and communication, set up in Bristol U.K. in 2000. The effectiveness of the training has been demonstrated in a large number of trials (https://www.promptnz.org/evidence-of-effectiveness). In 2017 PROMPT was introduced at the Hannover Medical School in Germany.

Shoulder dystocia is a rare but severe obstetrical emergency, leading to severe complications for the newborn, such as brachial plexus injury (BPI), brain damage due to hypoxia, and fetal death. It may also seriously
harm the mother. The actual incidence of shoulder dystocia is thought to be between 2-3% worldwide. Risk factors have been identified, such as fetal macrosomia, Type I diabetes or gestational diabetes, shoulder dystocia in a previous pregnancy, labour induction, epidural anaesthesia, vaginal operative delivery and very short and prolonged second stage of labour. However, these risk factors are of low predictive value, and many cases of shoulder dystocia are not associated with any of these parameters. Brachial plexus injury is the most common complication of shoulder dystocia, with an incidence of 0.5 to 4.0 per 1000 cases. It has been shown in many studies that the implementation of training can reduce the incidence of in BPIs. A retrospective cohort study by Draycott et al. found that practical training (PROMPT) led to a significant reduction of BPIs from 7.4% to 1.3% (p<0.01). After suitable training, they could even reduce permanent BPIs to 0%.

Third and fourth-degree Perineal Tears have a prevalence rate from 0.6% to 8%. Shoulder dystocia and internal manoeuvres were associated with a three-fold increase in the risk of OASIS (obstetric anal sphincter injuries). However, there are no studies investigating if training for managing shoulder dystocia can reduce birth injury III & IV° for the mother.

This is a prospective and retrospective observational cohort study to test the hypothesis that PROMPT Training minimises the mother’s permanent brachial plexus injury and birth injuries after 2 1/2 years of training at the Hannover Medical School.

**METHODS**

In this prospective observational cohort study we compared the frequencies of shoulder dystocia, permanent brachial plexus injury and birth injury III & IV following the introduction of PROMPT at the Hanover Medical School in 2017 with retrospective data from 2004.

All professional groups involved in labour and childbirth (40 obstetricians, 42 midwives, 4 neonatologists, 4 pediatric nurses, 7 anaesthetists, 6 anaesthesia nurses, and 6 theatre nurses) participated in the training.

The impact of training following its introduction was assessed by comparing complication rates before and after the implementation. All infants born during 16 years, from January 1st 2004, until December 31st 2019, were identified using a computerised fetal database (Viewpoint V.5 and V.6). In addition, all birth books from 2004 until 2019 were examined and checked by hand to identify further cases. All cases of neonates with suspected plexus injury following shoulder dystocia were followed up at the age of one year, and the outcomes were recorded. The study compared the period ‘before the training’ (group 1) and ‘after the training’ (group 2) regarding the number of shoulder dystocia cases, brachial plexus injuries, asphyxia, adverse outcomes as well as the frequency of the manoeuvres performed. In particular, the numbers of perineal tears grades III & IV, episiotomies and vaginal operative deliveries were compared.

**Statistical Methods:**

The statistical evaluation mainly employed basic descriptive statistics. For qualitative variables, absolute and per cent frequencies were given. The two study groups (before PROMPT-Training and after the initiation of the PROMPT-Training) were contrasted using contingency tables and tested for significant differences using the chi-square test or, if the expected frequencies proved too low, Fisher’s exact test was applied. Odds Ratios with 95% CI were calculated in case of significant differences. Relative risk reduction was also calculated for all qualitative parameters. Quantitative variables were presented as mean with standard deviation or median with range. They were tested for normal distribution using the Kolmogorov–Smirnov test. In case of significant deviations from the normal distribution, both groups were compared using the Mann–Whitney U test; otherwise, the independent samples t-test was used.

Statistical tests were performed two-sided at a significance level of 5%. Due to the descriptive nature of the present analysis, no alpha adjustment for multiple testing was applied, and the results were interpreted accordingly.

Statistical analyses were undertaken using IBM SPSS Statistics 26 (SPSS Inc., an IBM Company, Chicago,
Ethical approval was obtained from the Hannover Medical School Ethical Committee (Nr.8268 BO K 2019, 16th January 2019)

RESULTS

Shoulder Dystocia

The main findings were an increase in the diagnosis of shoulder dystocia (48/18.031 (0.27%) to 23/4.609 (0.50%), (p=0.017), OR 1.88, 95%-CI [1.14; 3.09]) and of Mc’Roberts manoeuvres (37/48 (77.1%) to 23/23 (100%) (p=0.013), OR 1.62, 95%-CI [1.33; 1.98]), whereas simultaneously the numbers of permanent brachial plexus injury (BPI) decreased (1/7 (14.2%) vs 0/1 (0%)). Also, the use of internal rotation manoeuvres and manual extraction of arms was improved (6/48 (12.5%) to 5/23 (21.7%) (p=0.319).

The total number of deliveries was 22,640. The diagnosis of shoulder dystocia before and after the training almost doubled (48/18.031 (0.27%) to 23/4.609 (0.50%) (p=0.017), OR 1.88, 95%-CI [1.14; 3.09]). BPIs decreased from (14.6%) to 1/23 (4.3%) (p=0.261). There was 1/7 (14.2%) of permanent BPI before and 0/1 (0%) cases after.

Besides BPI, the second most severe adverse outcome in shoulder dystocia was asphyxia, which had a long-term negative impact on the newborn and the family. Here, the results were unexpected as birth asphyxia increased substantially from 3/48 (6.3%) to 4/23 (17.4%) (p=0.23), however looking at the one-year outcome for adverse effects of asphyxia, there was only 1 case. The single child affected suffered from recurrent pneumonitis.

The most important finding for manoeuvres was a statistically significant increase in performing McRoberts (37/48 (77.1%) to 23/23 (100%) (p=0.013), OR 1.62, 95%-CI [1.33; 1.98]) and a clinical increase in suprapubic pressure (13/48 (27.1%) and after 7/23 (30.4%) (p=0.784)). Also, internal rotational manoeuvres, including manual extraction of the arm, were more frequently applied (6/48 (12.5%) before and 5/23 (21.7%) after (p=0.319)), which was, however, not statistically significant.

Table 1. Shoulder Dystocia Complications, Adverse Outcomes and Manoeuvres applied.

The descriptive analysis showed no significant differences between training groups regarding gestational age, gravida, para and birthweight, indicating similarity between both populations.

The outcome parameters 5’ APGAR-score, umbilical artery pH, base excess and blood loss were similar and slightly worse in group 2 (base excess and blood loss), indicating either higher blood loss or improved estimation and recordings of blood loss. There were no statistically significant differences between the two Groups.

Table 2. Laboratory parameters and demographic characteristics.

In detail, we observed an increase in the cases with 5’ APGAR-score <7 from 4/48 (8.3%) to 4/23 (17.4%). An increase of umbilical artery pH [7.10 from 7/47 (14.9%) to 4/23 (17.4%), an increase of the base excess [7.12 from 6/47 (12.8%) to 4/23 (17.4%), as well as an increase in blood loss [500 ml from 2/48 (4.2%) to 3/23 (13%), was noticed. The percentage of nulliparous women with shoulder dystocia increased from 19/48 (39.6%) to 12/23 (52.2%). Also, the proportion of women in post-term pregnancies ([?]+40 wks of gestation) increased from 21/48 (43.8%) to 12/23 (52.2%). However, the mean birthweight was slightly reduced from 4,062.5 g to 3,910 g (3.8% RRR).

Perineal Tears grades III & IV

The main findings following the training are a substantial decrease in episiotomies (5,267/18,031 (29.2%) to after 836/4,609 (18.1%) (p<0.001), OR 0.54, 95 %-CI [0.49, 0.58]). In contrast, the total number of perineal tears grades III & IV increased (92/17.939 (0.5%) to after 39/4.570 (0.85%) (p=0.007) OR
However, perineal tears grades III & IV following shoulder dystocia were not significantly different: there was a slight increase from 1/48 (2.1%) before to 1/23 (4.3%) after (p = 0.546). The percentage of vaginal operative deliveries remained relatively constant (before 1178/18031 (6.5%) and after 324/4609 (7%)).

The number of perineal tears grades III & IV following spontaneous delivery, excluding vaginal operative deliveries, increased (71/16,853 (0.42%) to after 26/4,285 (0.60%). Again, this was statistically not significant (p=0.1).

From the total vaginal operative deliveries alone, we observed a significant increase in the frequency of perineal tears grades III & IV (21/1.178 (1.78%) to after 13/324 (4.0%). This was also not statistically significant (p=0.017) OR 2.3 95%-CI [1.14; 4.65]).

Table 3. Perineal Tears IIIdeg/IVdeg, Episiotomies, Vaginal operative Deliveries

The descriptive analysis of both Groups showed no demographic differences between the populations.

Table 4. Demographic characteristics

We applied the national policy and did not apply routine episiotomy in every case of operative vaginal delivery. As a result, while the number of vaginal operative deliveries remained constant, episiotomies decreased substantially, and perinatal tears grades III & IV increased.

DISCUSSION:

Main Findings

After 21/2 years of PROMPT training, the total BPIs were reduced from 14.6% to 4.3% and permanent BPIs from 14.28% to 0%. Simultaneously, McRoberts’ manoeuvre increased from 77.1% to 100%. During this period, episiotomies went from 29.1% to 18.1% (p<0.001) but total perinatal tears degIII/IV increased from 0.5% to 0.85% (p=0.007). Base excess and blood loss went up slightly (n.s.).

PROMPT brakes with the dogma that rare but severe obstetrics complications can not be trained. Specific manoeuvres such as McRoberts, suprapubic pressure, internal rotation, delivery and the development of the posterior arm are well-established to resolve the emergencies, and positive effects have been demonstrated 5,8. Following PROMPT, we observed an increase in the initiation of these manoeuvres, particularly the use of McRoberts manoeuvre in 100% of cases. Also, factors promoting brachial plexus injury were abandoned. These results show a very promising impact of the training and are the study’s most important findings. Ongoing annual training is however mandatory to make these results sustainable.

The percentage of vaginal operative births remained unchanged before and after the training at around 7%, while the mean fetal weight increased slightly from 3,517 g to 3,604 g. Simultaneously, the incidence of vaginal operative deliveries resulting in third and fourth-degree tears increased from 1.8% to 4% after the training. This finding may be the result of reduced use of episiotomy. However, other factors, such as an increase in diabetes and obesity, mean maternal age and the improvement in documentation following the PROMPT-Training, may have a role.

Strengths and Limitations

The main strength of our research was that it was conducted in a large obstetric centre with around 3000 births annually. A search of the database and all birth hard copy recordings from 2004 providing us with comprehensive data. Also, the training concept included all professional groups involved in labour and childbirth (obstetricians, midwives, neonatologists, paediatric nurses, anaesthetists, anaesthesia nurses, and theatre nurses). Therefore the whole team worked together using the same management algorithms. The training was repeated four times annually.

Several limitations have to be mentioned. Firstly, the participation level of staff was low. Over the 2 1/2-year period, we observed a total participation rate of only 35.6%. However, among the core staff involved,
the participation rates were significantly higher, with obstetricians achieving a rate of 50-60% and midwives of 92-100%.

Secondly, there was a low total number of rare obstetrical complications such as shoulder dystocia cases (71/22,640) and IIIdeg/IVdeg perineal tear cases (131/22,640), limiting the conclusions that can be drawn from this cohort.

**Interpretation**

The authentical use of a scientifically written and effective training concept, the adaptation of the training materials into the German language taking into account German guidelines and drugs, the use of high fidelity simulators and the implementation of the PROMPT-Training concept involving teams of midwives, obstetricians, paediatricians and anesthesiologists on a labour ward with more than 3,000 deliveries per annum and with a wide variety of high-risk pregnancies, such as the Hannover Medical School, has resulted in significant improvements after only two and a half years. This approach can reduce permanent brachial plexus injury in shoulder dystocia to zero.

The findings of the PROMPT introduction at a German-speaking university hospital show substantial benefits. Albeit in a relatively small number of cases, the cohort represents the clinical reality in a German setting rather well.

**CONCLUSION:**

PROMPT significantly improves the management of shoulder dystocia and decreases permanent brachial plexus injuries, but not perinatal tears IIIdeg/IVdeg.

**Acknowledgements**

We want to thank Frau Regina Jager for organising the in-house training and Ulrike von Hehn (Medistat GmbH, Konigsfurt 6, 24796 Klein Konigsforde / Krummwisch, Germany) for the statistical analysis. We would also like to thank Dr. rer. nat. Steven R Talbot, Data Scientist, for critical comments.

**Disclosure of interests**

There are no conflicts of interest. Completed disclosure of interest forms are available as supporting information.

**Contribution to authorship**

CvK is the founder and CEO of PROMPT Germany gUG (haftungsbeschrankt) and has introduced the concept in Hannover, Germany. SP did a research project comparing outcomes before and after the introduction of the training. SP drafted the manuscript with substantial changes by CvK. Subsequently, the manuscript was critically reviewed and revised by LB, BB, HL and MF. SP collated the data, and SP and CvK analysed the data and produced the tables.

**Details of ethics approval**

Ethical approval was obtained from the Hannover Medical School Ethical Committee (Nr. 8268 BO K 2019, 16th January 2019).

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**References:**


Table Caption List:
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