

Til Styrelsen for Patientsikkerhed

d26/11 2019



Uddybelse af DASA IMs høringssvar d 18/9 2018 vedrørende omskæring af drenge.

Dansk Selskab for Anæstesiologi og Intensiv Medicin vil indledningsvis gerne takke for muligheden for at uddybe vores høringssvar samt for mulighed for deltagelse i arbejdsgruppen vedrørende dreng omskæring.

Omskæring af drengebørn på lægelig indikation i forbindelse med sygdomme udføres udelukkende i generel anæstesi i det danske sundhedsvæsen.

Generel anæstesi til børn kan foregå på sikker vis når de rette kompetencer og det rette udstyr er tilstede, på det rette sted.

DASA IM tilslutter sig Safetots.org initiativet, (<https://www.safetots.org>) som blandt andet på baggrund af anerkendelse af FN's børnekonvention (UNCRC) og EACH charteret (1988) anbefaler, børne-kompetent anæstesiolog til alle børn under 3 år.. Safetots.org initiativet understøttes af europæiske og internationale anæstesiologiske selskaber (European Society for Paediatric Anaesthesiology (ESPA), Association Des Anesthésistes-Réanimateurs Pédiatriques d'Expression Française, Società di Anestesia e Rianimazione Neonatale Pediatrica Italiana, Asociación de Anestesia, Analgesia y Reanimación de Buenos Aires).

Litteraturen beskriver forskellige former for lokalbedøvelse til omskæring af drenge, men ingen af disse giver fuldstændig smertefrihed: Brady-Fryer B, Wiebe N, Lander JA. Pain relief for neonatal circumcision. Cochrane review 2004).

Forfatteren konkluderer at ingen af de anvendte former for lokalbedøvelse giver fuldstændig smertefrihed under omskæring.

DASA IM finder det under faglig standard at udføre en smertefuld kirurgisk procedure på børn uden sufficient smertedække.

Uanset indikation (medicinsk eller rituel) har DASA IM den holdning, at alle børn har krav på sikker kirurgi under fuldstændig smertefrihed. Dette kan ifølge DASA IM kun foregå i en kombination af generel og regional anæstesi.

Vi har både i Danmark og i vores nabolande set tilfælde af livstruende komplikationer i forbindelse med lokalanæstetiske midler. Både i form af methæmoglobinæmi ved prilocain samt systemisk toxicitet af lokalanæstetika. Komplikationerne inkluderer kredsløbssvigt, bevidstløshed og kramper samt iltmangel.

Vi skal i den forbindelse opfordre til at Styrelsen for Patientsikkerhed i forbindelse med tilsyn påser at følgende er opfyldt:

- Mundtlig og skriftlig information af forældre om plan for smertebehandling.
- Mundtlig og skriftlig information af forældre om observation af bivirkninger til smertebehandling.
- Tilstedeværelser af læge med kompetencer i behandling af børn med komplikationer til smertebehandling. Herunder kompetencer i behandling af kramper og kredsløbssvigt.

Styrelsen spørger ind til 2 forhold, som er følger af utilstrækkelig analgesi ved omskæring af små børn:

1. Følger af utilstrækkelig analgesi. (Hvis barnet ikke er tilstrækkelig anæstetiseret og smertelindret i forbindelse med det kirurgiske indgreb må man antage at barnet er blevet ufrivilligt fastholdt af voksne personer under indgrebet)
2. Følger af fastholdelse af børn.

Ad. 1. Følger på sigt af ubehandlet smerte hos nyfødte. Se bilag 1.

DASAIM forholder sig til at der er human og dyreeksperimentel forskning som tyder på skadelige langtidsfølger af ubehandlet smerte hos nyfødte børn/forsøgsdyr.

Ad. 2. Følger af ufrivillig fastholdelse. Se bilag 2.

DASAIM forholder sig til at ufrivillig fastholdelse må formodes at finde sted ved mangelfuld analgesi under omskæring af drenge. DASAIM bekendt er dette ikke undersøgt hos nyfødte. Der foreligger dog en del pædiatrisk litteratur, som dokumenterer skadelige følger af ufrivillig fastholdelse hos børn.

Effect of Restraint Use on Family. Se bilag 3.

DASAIM forholder sig til at der foreligger forskning, som dokumenterer skadelige følger for børn som følge af ufrivillig fastholdelse i forbindelse med medicinske procedurer og kirurgiske operationer. Desuden kan fastholdelse have konsekvenser for forholdet mellem barn og forældre.

Konklusion

Planlagt kirurgi uden de ovenfor nævnte anbefalinger anses af DASAIM for at være væsentligt under faglig standard. DASAIM vil anbefale Styrelsen for Patientsikkerhed at være opmærksom på ovennævnte forbehold når Styrelsen udfører tilsyn på klinikker og hospitaler. Læger der udfører planlagt kirurgi på utilstrækkeligt bedøvede børn bør undergå et fagligt tilsyn. Såfremt der ikke omgående rettes op og sikres moderne og sufficient behandling af denne patient gruppe bør der gennemføres virksomhedsindskrænkning og eventuelt permanent autorisationsfratagelse.

Når den færdige rapport foreligger, forventer vi at have haft mulighed for at godkende den faglige rådgivning vi eventuelt tages til indtægt for. Såfremt vores råd ikke følges, har vi fortsat et stort ønske om at vores faglige rådgivning som minimum fremgår af et bilag.

Bilag 1:

Fra: Maria Fitzgerald. THE DEVELOPMENT OF NOCICEPTIVE CIRCUITS. Review. NATURE REVIEWS | NEUROSCIENCE VOLUME 6 | JULY 2005.

“Increasing awareness of activity dependent and injury-related plasticity in the newborn CNS has highlighted the possibility that early tissue injury can affect future pain processing through developmental alterations in nociceptive circuitry” (Grunau, R. Early pain in preterm infants. A model of long-term effects. *Clin. Perinatol.* 29, 373–394;(2002).

“Many preterm infants receive numerous invasive procedures in intensive care and it is not always possible to achieve adequate levels of analgesia. There is evidence from both animal models and humans that these early pain experiences might alter subsequent CNS function” (Grunau, R. Early pain in preterm infants. A model of long-term effects. *Clin. Perinatol.* 29, 373–394; (2002). Anand, K. J. Pain, plasticity, and premature birth: a prescription for permanent suffering? *Nature Med.* 6,971–973 (2000). Peters, J. W. *et al.* Does neonatal surgery lead to increased pain sensitivity in later childhood? *Pain* 114, 444–454 (2005)).

“Although many of the nervous system responses to local tissue damage resolve after the injury has healed, tissue damage during a critical period in newborn rodents can cause prolonged alterations in somatosensory function, which last into adult life. The consequences of neonatal injury in rodents depend on the type of injury and the modality of sensation under investigation. Repetitive paw needle prick in the first postnatal week produces heat hyperalgesia several weeks later” (Anand, K. J., Coskun, V., Thirivikraman, K. V., Nemeroff, C. B. & Plotsky, P. M. Long-term behavioral effects of repetitive pain in neonatal rat pups. *Physiol.Behav.* 66, 627–637 (1999). Johnston, C. C. & Walker, C. D. The effects of exposure to repeated minor pain during the neonatal period on formalin pain behaviour and thermal withdrawal latencies. *Pain Res. Manag.* 8, 213–217 (2003).)

“Neonatal hindpaw inflammation has a pronounced effect on the behavioural and dorsal horn cellular response to a second inflammatory challenge well into adulthood” (Ren, K. *et al.* Characterization of basal and re-inflammation-associated long-term alteration in pain responsivity following short-lasting neonatal local inflammatory insult. *Pain* 110, 588–596 (2004). Ruda, M. A., Ling, Q. D., Hohmann, A. G., Peng, Y. B. & Tachibana, T. Altered nociceptive neuronal circuits after neonatal peripheral inflammation. *Science* 289, 628–631 (2000). Tachibana, T., Ling, Q. D. & Ruda, M. A. Increased Fos induction in adult rats that experienced neonatal peripheral inflammation. *Neuroreport* 12, 925–927 (2001).

“Chemical or mechanical irritation of the colon in P8–21 rats, on the other hand, produces a persistent visceral hypersensitivity in the adult” (Al Chaer, E. D., Kawasaki, M. & Pasricha, P. J. A new model of chronic visceral hypersensitivity in adult rats induced by colon irritation during postnatal development. *Gastroenterology* 119, 1276–1285 (2000).

“Skin wounds in the newborn also have prolonged effects: the skin remains hypersensitive long after the wound has healed” (Reynolds, M. L. & Fitzgerald, M. Long-term sensory hyperinnervation following neonatal skin wounds. *J. Comp. Neurol.* 358, 487–498 (1995).)

“The size of the dorsal horn receptive field increases for at least six weeks following injury” (Torsney, C. & Fitzgerald, M. Spinal dorsal horn cell receptive field size is increased in adult rats following neonatal hindpaw skin injury. *J. Physiol. (Lond.)* 550, 255–261 (2003).

“A clear-cut example of a central adaptive response to neonatal injury is seen following peripheral nerve damage. Although partial peripheral nerve damage in adult rodents causes significant and prolonged neuropathic pain behavior, which is characterized by marked allodynia, this does not occur in rat pups up to the age of P21.” (Howard, R. F., Walker, S. M., Mota, M. & Fitzgerald, M. The ontogeny of neuropathic pain: postnatal onset of mechanical allodynia in rat spared nerve injury (SNI) and chronic constriction injury (CCI) models. *Pain* 115, 382–389 (2005).)

Endelig er der en del litteratur om følger af procedure-relateret smerte hos børn:

- Wintgens A, Boileau B, Robaey P. Posttraumatic stress symptoms and medical procedures in children. *Can J Psychiatry* 1997; 42:611–616.
- Taddio A, Shah V, Gilbert-MacLeod C, Katz J. Conditioning and hyperalgesia in newborns exposed to repeated heel lances. *JAMA* 2002; 288:857–861.
- Weisman SJ, Bernstein B, Schechter NL. Consequences of inadequate analgesia during painful procedures in children. *Arch Pediatr Adolesc Med* 1998; 152:147–149.
- Bienvendu OJ, Eaton WW. The epidemiology of blood-injection-injury phobia. *Psychol Med* 1998; 28:1129–1136.
- Caes L, Goubert L, Devos P, et al. The relationship between parental catastrophizing about child pain and distress in response to medical procedures in the context of childhood cancer treatment: a longitudinal analysis. *J Pediatr Psychol* 2014; 39:677–686.
- Brodzinski H, Iyer S. Behavior changes after minor emergency procedures. *Pediatr Emerg Care* 2013; 29:1098–1101.
- Power NM, Howard RF, Wade AM, Franck LS. Pain and behaviour changes in children following surgery. *Arch Dis Child* 2012; 97:879–884.
- Beaton L, Freeman R, Humphris G. Why are people afraid of the dentist? Observations and explanations. *Med Princ Pract* 2014; 23:295–301.
- Taddio A, IppM, Thivakaran S, et al. Survey of the prevalence of immunization noncompliance due to needle fears in children and adults. *Vaccine* 2012; 30:4807–4812.
- McMurtry CM, Pillai Riddell R, Taddio A, et al. Far from 'just a poke': common painful needle procedures and the development of needle fear. *Clin J Pain* 2015; 31 (10 Suppl): S3–S11.

Bilag 2:

"Restraint (in terms of the effects it has) has been associated with speech and language problems, a negative self-image, fear of and distrust of medical care, and with post-traumatic stress disorder". (Brenner M. 'Child restraint in the acute setting of pediatric nursing: an extraordinarily stressful event'. *Issues in comprehensive pediatric nursing*. 2007;30(1-2): 29-37.)

"According to pediatric nurses, restraint is more traumatic for a child than the treatment itself" (Robinson S, Collier J. 'Holding children still for procedures'. *Paediatric nursing*. 1997;9(4): 12-14.)

"Longitudinal research with leukemia patients has shown that any participation by parents in restraint has a negative effect on the relationship with their child". McGrath P, Forrester K, Fox-Young S, Huff N. "Holding the child down" for treatment in paediatric haematology: the ethical, legal and practice implications. *Journal of law and medicine*. 2002;10(1): 84-96.

Effect of Restraint Use on Children (Piet Leroy).

"The use of restraint with children is not beneficial and also is extraordinarily stressful" (Masters, 1998; Mohr WK, Mahon MM, Noone MJ. A restraint on restraints: the need to reconsider the use of restrictive interventions. *Arch Psychiatr Nurs*. 1998 Apr;12(2):95-106. Martinez RJ, Grimm M, Adamson MJ. From the other side of the door: patient views of seclusion. *Psychosoc Nurs Ment Health Serv*. 1999 Mar;37(3):13-22.)

"This is supported by discourse that suggests that children find the experience of being restrained much more distressing than the pain involved in the treatment or procedure that prompted the use of restraint." (Collier J, Pattison H. *Paediatr Nurs*. Attitudes to children's pain: exploding the 'pain myth'. 1997, Dec;9(10):15-8; Folkes KIs restraint a form of abuse? *Paediatr Nurs*. 2005 Jul;17(6):41-4.)

"Although few data are available, some authors have hypothesized about the long-term consequences of restraint on hospitalized children. For example, Siblinga and Friedman (1971) suggested that language deficits and delayed speech may occur as a result of restraint use, while others hypothesized that a relationship existed between use of restraint, loss of motor strength, and negative body image". (Dowd EL, Novak JC, Ray EJ. Releasing the hospitalized child from restraints. *MCN Am J Matern Child Nurs*. 1977 Nov-Dec;2(6):370-3.)

"Twenty years later, Selekman and Snyder proposed that psychological problems such as future fears and impact on trusting relationships also may be issues of concern related to the use of restraint" (AACN Clin Issues. 1996 Nov;7(4):603-10.) Uses of and alternatives to restraints in pediatric settings).

"They also hypothesized about a link between increased stress and the disease process. Other authors have suggested that restraint of children may lead to cumulative retraumatization and post-traumatic stress disorder (PTSD), physical discomfort, unexpected death, and asphyxia" (Masters, 1998; Kennedy SS, Mohr WK. *Am J Ortho-psychiatry*. 2001 Jan;71(1):26-37. A prolegomenon on restraint of children: implicating constitutional rights.)

Bilag 3.

“At a time when family-centered care is advocated and encouraged, examination of the outcomes of child restraint on parents has been neglected.” (McGrath P, Huff N. Aust J Holist Nurs. 2003 Oct;10(2):5-10. Including the fathers' perspective in holistic care. Part 2: Findings on the fathers' hospital experience including restraining the child patient for treatment.; Moscardino U, Axia G. Infants' responses to arm restraint at 2 and 6 months: a longitudinal study. Infant Behav Dev. 2006 Jan;29(1):59-69.).

“Fathers' experience of restraining their children for oncology treatment was explored by McGrath and Huff (2003). The investigators reported that witnessing and being involved in invasive procedures was the most challenging and emotionally traumatic aspect of hospitalization for fathers.

The study concluded that not all parents were happy to, or should be coerced into, assisting staff to hold their children during a procedure. Parental distress also was a theme that emerged from a more recent study related to child restraint “ (Moscardino U, Axia G. Infant Behav

Dev. 2006 Jan;29(1):59-69. Infants' responses to arm restraint at 2 and 6 months: a longitudinal study.), whose purpose it was to confirm theories of child development by examining infant response to restraint. Fifty-two infants were examined at two months and six months of age to determine differences in infant response to restraint during the four-month period. However, 33 percent of the infants did not complete the study, as involvement was too distressing for the infants and their parents. This report highlights some of the distress surrounding the use of restraints.”

“Although many authors suggest alternatives to restraint, there is scant research in this area. In child psychiatry, there is no mention of anticipatory interventions, and practice parameters of the American Academy of Child and Adolescent Psychiatry (AACAP) offer only vague guidance to forestall aggressive behavior in children (AACAP, 2000). However, it is noted that the AACAP works continuously with parents, former child psychiatry patients, and staff to review its recommendations in relation to restraint. The literature suggests that a variety of alternatives, such as distraction, play therapists, the use of parents, improved pain relief, and behavioral interventions, could lead to less restraint in practice (McCarthy, Cool, & Hanrahan, 1998; Dorfman, 2000; Martin, 2002; McGrath and Huff, 2003; Meunier-Sham & Ryan, 2003; Tomlinson, 2004; Willock, 2004; Piira, Sugiura, Champion, Donnelly, & Cole 2005). Although other publications provide practical decision-making frameworks and clinical practice benchmarks to guide nurses towards the most appropriate strategy when immobilization may be required (Bland, Bridge, Cooper, Dixon, Hay, & Zerbato 2002; Jeffrey, 2002; Lambrenos & McArthur, 2003; Folkes, 2005), there is a dearth of empirical data that comprehensively explores alternatives to the use of restraint in children.

Folkes (2005) developed a decision-making algorithm that highlights the importance of the child's assent and/or consent, staff explanations, and use of alternatives to restraint. This tool also offers a pathway in an emergency situation whereby restraint may be required. The final part of the algorithm highlights the importance and necessity of documentation. Documentation also is the key focus of an article by Jeffrey (2002), who offers a broader framework for nurses considering the use of restraint. According to Jeffrey (2002), the key to decision-making and restraint is reliant on two areas: thorough assessment of the child's current needs and appraisal of documentation regarding the results of any previous immobilization or restraint of the child.