HK J Paediatr (new series) 2021;**26**:141-148

Original Article

Comparison of Alcohol and Phenol Neurolysis in Children with Spasticity: A Pilot Matched Controlled Trial

KY **LEUNG**, WK **CHAN**, WK **MAN**, CH **KO**

Abstract ***Purpose:*** To evaluate the effectiveness of phenol and alcohol neurolysis as treatment of spasticity. ***Method:*** This is a non-randomisred matched controlled trial. Non-ambulatory spastic children were given same volume of phenol to one nerve and alcohol to the contralateral nerve. Spasticity were assessed by passive range of movement and Modified Ashworth Scale before treatment, and at one, three and six months after treatment. ***Findings:*** Five pairs of obturator nerves and one pair of musculocutaneous nerves were recruited. Both phenol and alcohol neurolysis were found to be effective to reduce spasticity at one month, with no significant inter-group difference in passive range of movement gain and Modified Ashworth Scale reduction. No significant complication was identified. ***Conclusion:*** Both phenol and alcohol are effective treatment of focal spasticity in children. As a nerve blocking agent, alcohol is a safe and effective alternative to replace phenol in paediatric patients.

Key words *Alcohol; Cerebral palsy; Neurolysis; Phenol; Spasticity*

Introduction

Spasticity results from the loss of inhibition of motor neurons, causing excessive velocity-dependent increase in resistance to movement.[1] Spasticity causes functional disability, pain and even joint deformity.[2] Spasticity can also cause difficulty in maintaining hygiene, development of pressure sores and increase risk of osteoporotic bone fracture during daily care procedure.[3]

The goals for tone reduction treatment include functional improvement, ease of care, and prevention of secondary pain, contractures and orthopaedic problems. Conventional approach includes physiotherapy, occupational therapy and use of orthosis to maintain range of joint motions and function. At later stage, orthopaedic surgery helps correct secondary lever arm deviations. Generalised and focal spasticity may be reduced by oral drugs, local injections by phenol, alcohol or botulinum toxin, selective dorsal rhizotomy and intrathecal baclofen.[1] Oral medications are commonly used in cerebral palsied children with generalised spasticity. Dose escalation is often limited by significant systemic side effects. Rhizotomy surgery and intrathecal baclofen implantation are invasive and largely irreversible; careful selection of appropriate candidates is mandatory to achieve optimal therapeutic effect. Local injection is a widely approved modality of treatment for focal spasticity. Chemodenervation refers to interruption of nerve-muscle transmission with an injectable agent. Botulinum toxin A

Department of Paediatrics and Adolescent Medicine, Princess Margaret Hospital, 2-10 Princess Margaret Hospital Road, Lai Chi Kok, Kowloon, Hong Kong SAR, China

KY **LEUNG**（梁潔欣） *FHKAM(Paediatrics), FHKPaed, MRCPCH*
WK **CHAN**（陳永祺） *FHKAM(Paediatrics), FHKPaed, MRCPCH*

Department of Physiotherapy, Caritas Medical Centre, 111 Wing Hong Street, Shamshuipo, Kowloon, Hong Kong SAR, China

WK **MAN**（文偉麒） *MSc*

Department of Paediatrics and Adolescent Medicine, Caritas Medical Centre, 111 Wing Hong Street, Shamshuipo, Kowloon, Hong Kong SAR, China

CH **KO**（高震雄） *FHKAM(Paediatrics), FRCP (Glasg)*

Correspondence to: Dr KY **LEUNG**
Email: kymelody@gmail.com

Received February 26, 2019

exerts the effect by causing neuromuscular blockage while phenol and alcohol injections cause neurolysis. Phenol and alcohol injection have a lower cost and faster onset of action compared to botulinum toxin A injection.[3-5] In addition, a good nerve block may achieve better tone reduction effect than botulinum toxin A, and the effect may last longer. The technique is demanding; common complications include pain and transient dysaesthesia.[3,5] Common nerves for neurolysis include the musculocutaneous nerve in prominent elbow flexion, and the obturator nerve in excessive hip adduction. Clinical applications also include ankle plantarflexion (gastrocnemius branches of posterior tibial nerve) and shoulder adduction (thoracodorsal nerve).

Phenol causes nerve destruction by inducing protein precipitation. There is loss of cellular fatty elements, separation of the myelin sheath from the axon, and axonal oedema.[4] Alcohol causes nerve coagulation and muscle necrosis by denaturing proteins and is more efficient in destroying cell bodies, with resultant Wallerian degeneration and tissue fibrosis.[4] Phenol in concentration between 5% and 7% and alcohol in concentration of 45-100% are used for neurolysis.[5] Injections are given in specific nerve after identifying the nerve by electrical stimulation. While both agents are widely approved for focal spasticity, there are limited studies to compare the clinical efficacy between phenol and alcohol for neurolysis in paediatric patients.[6,7] There is only one study comparing phenol and alcohol neurolysis of tibial nerve for treatment of spastic foot after stroke in adult.[8] As there has been a world-wide shortage in supply of therapeutic phenol since the fall of 2016, many centres have to administer alcohol as an alternative. The aim of this study is to ascertain the effectiveness and safety of alcohol as compared to phenol as a neurolysis agent for treatment of childhood spasticity.

Methods

Study Design and Setting

This is a non-randomised matched controlled trial conducted in a paediatric rehabilitation unit in Caritas Medical Centre in Hong Kong. All eligible patients were spastic children recruited during the study period from October to December in 2016. Patients who were on oral anti-spasticity medications did not have dose adjustment within three months before the procedure. The study protocol was approved by Kowloon West Cluster Research Ethics Committee of Hospital Authority.

Subjects

Nerve pairs of paediatric patients given 5% phenol injection (minimal 0.5 ml, maximum 1 ml) to one side and same volume of 50% or 75% alcohol injection to the contralateral side were recruited with following inclusion and exclusion criteria:

Inclusion criteria:
- Age ≤18 years old
- Presenting with excessive bilateral hip adductor spasticity and/or bilateral elbow flexion spasticity
- Bilateral involvement with similar baseline tone between the left and right extremities in the same patient
- Informed Consent for the procedure obtained from patient's family
- Able to tolerate physiotherapy for treating spasticity

Exclusion criteria:
- Unstable medical condition
- Unilateral spasticity
- Received recent phenol injection / alcohol injection (within 12 months)
- History of adverse reaction to phenol or alcohol

Injection Protocol

All procedures were performed by same operator. The supervising neurologist (CHK) would randomly draw the side (right or left) to receive phenol, and the other side would be assigned for alcohol. Both operator and assessor were blinded to the assignment, which was concealed until data analysis. Twenty-two gauge Teflon coated needles were used. The needle hub of the needle was connected to the nerve stimulator (Nicolet Viking Electrodiagnostic Unit). The nerve blocks were performed under electric nerve stimulation. Once the nerve was localised as evidenced by contractions of the adductor muscle (for obturator nerve) or biceps muscle (for musculocutaneous nerve), the needle position was adjusted until minimum current was needed to produce traction, suggesting that the level of the needle was close enough to the nerve. At this point, the neurolytic agent (5% phenol) from a syringe connected to a needle was injected slowly until abolition of muscle contraction was obtained. The same volume of alcohol at 50-75% was subsequently injected to the contralateral nerve under similar techniques.

Outcome Measures

Primary outcomes include (1) Passive range of movement (PROM) of hip abduction / elbow extension and

(2) Modified Ashworth Scale (MAS) (Appendix 1) of bilateral hip adductor / biceps. Assessment of patient was performed by an independent physiotherapist before treatment, 1 month, 3 months and 6 months after treatment. The assessor was blinded to the agents being injected into either side of the same patient. Secondary outcome is the incidence of complications such as paraesthesia, local reactions, compartment syndrome, and infection related to the procedure.

PROM of hip abduction with knee in 90-degree flexed position and with knee in neutral position were assessed and documented by the assessor. Hip abduction with knee in 90-degree flexed position were used for statistical analysis unless assessment was not possible due to the physical condition of the patient. In those cases, PROM of hip abduction with knee in neutral position were used.

Data Collection

Demographic data including age, sex and background medical history was obtained from the electronic patient record system. Physiotherapy assessment notes were retrieved to obtain the primary outcome.

Statistical Analysis

Data analysis was performed using SPSS for Windows, version 22. A p value <0.05 was considered statistically significant. Overall changes in the muscle tone and range of movement were analysed by Friedman test. Wilcoxon's sign rank test was used as to determine differences between the various time-points in the post-treatment period compared with pre-treatment measurements within a single treatment group. Mann-Whitney-U test was used to compare the effect between the two treatments at same post-treatment time points.

Sample Size Estimation

Lehmann[9] recommends that when using a nonparametric test, the researcher should first compute the sample size required for the parametric equivalent and then add 15% as an adjustment. Running a power analysis on a repeated measures Friedman ANOVA with eight measurements, a power of 0.80, an alpha level of 0.05, and a large effect size (f=0.40), the required sample size is seven.[10]

Results

Demographic Variables

A total of six patients with eight pairs of nerve received both phenol injection and alcohol injection were assessed during the study period. Among them, two patients received injection over obturator nerves and musculocutaneous nerves. Two pairs of nerves failed to meet all the inclusion criteria. Finally, six subjects (four male and two female) were recruited with five pairs of obturator nerves and one pair of musculocutaneous nerves (Figure 1). The mean age was 8.15 years (range 3.96-16.35). All subjects suffered from chronic spasticity. Five subjects had cerebral palsy and one had syringomyelia. Two of them were classified at level III Gross Motor Function Classification system (GMFCS) and the remaining three were classified at level V with long-term residential care.

Clinical Variables

The results of each individual subjects were summarised in Table 1.

Phenol Group

Table 2 shows the clinical outcomes at various post-injection time-points in the two groups. For PROM, difference in PROM at different time-points of assessment was screened with Friedman test (p=0.011). The gain in PROM at one month post injection was statistically significant (p=0.034). However, no statistical significance was found when compared to pre-treatment at three months (p=0.713) and six months (p=0.713) post injection.

For tone reduction with assessment by MAS, Friedman test revealed significant difference in MAS at different time-points of assessment (p=0.010). The reduction in MAS at one month post injection was statistically significant (p=0.034). However, change in MAS was found to have no statistical significance when compared to pre-treatment at three months (p=0.059) and six months (p=0.317) post injection.

Alcohol Group

For alcohol injection, the findings were similar as phenol injection. Friedman test revealed significant difference in PROM at different time-points of assessment (p=0.002). The improvement in PROM at one month post injection was statistically significant (p=0.024) and PROM was found to have no statistically significant difference compared to pre-treatment at three months (p=0.180) and six months (p=0.180) post injection.

For MAS, Friedman test showed significant difference in the MAS at different time-points of assessment (p=0.004). The reduction in MAS at one month post injection was

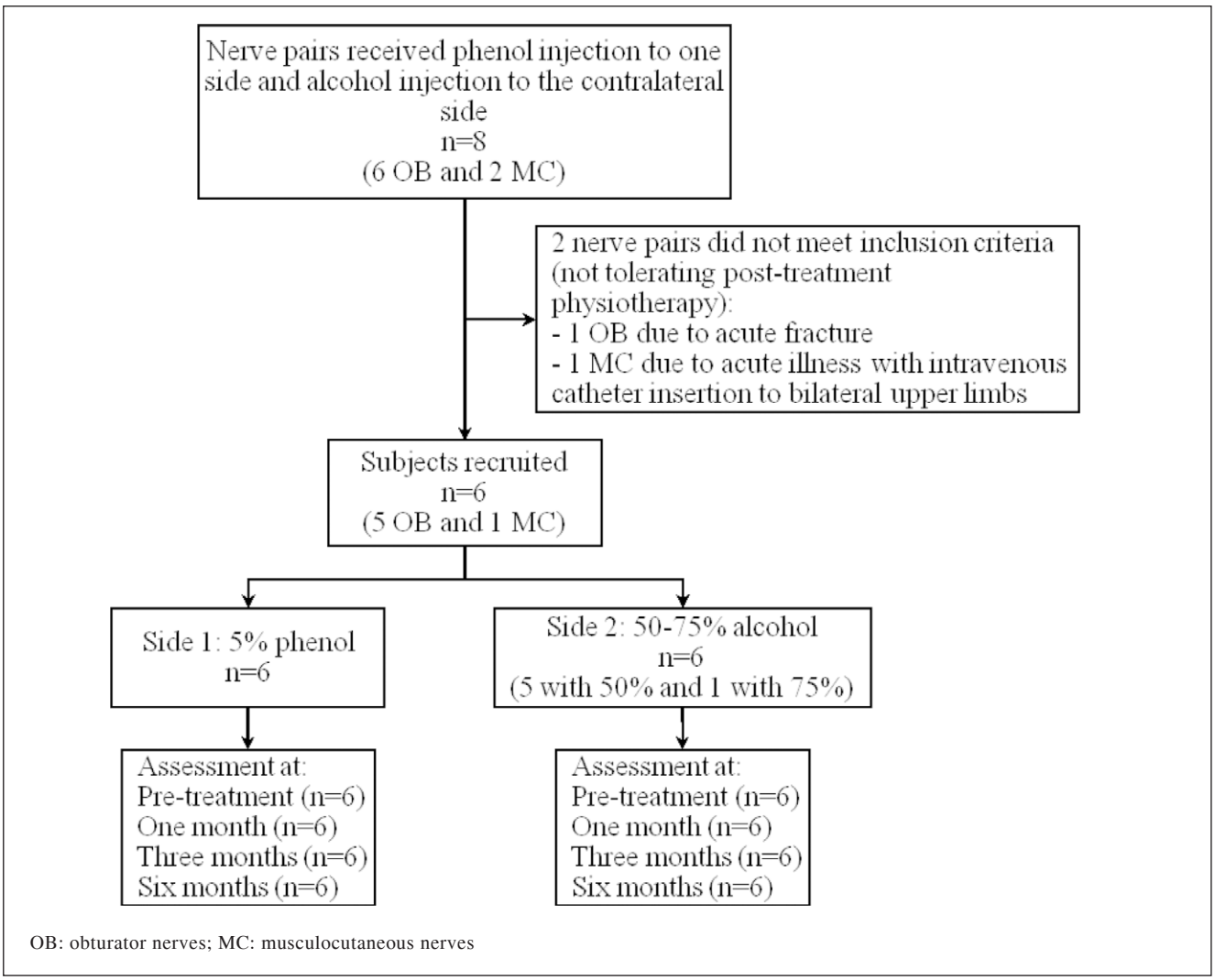

Figure 1 Subject enrolment and follow-up.

Table 1 Summary of the results of each individual subjects

Subject	Age	Diagnosis	Target nerve	Intervention group	Outcome at various time points							
					Pre-treatment		One month		Three months		Six months	
					PROM	MAS	PROM	MAS	PROM	MAS	PROM	MAS
1	6.67	Cerebral palsy	OB	Phenol	30	2	40	1.5	30	2	30	2
				Alcohol	30	2	40	1.5	30	2	30	2
2	16.35	Syringomyelia	OB	Phenol	30	3	40	2	30	2	30	3
				Alcohol	30	3	40	2	30	2	30	3
3	3.96	Cerebral palsy	OB	Phenol	10	2	20	1	15	1.5	15	2
				Alcohol	15	2	20	1	15	1.5	15	2
4	6.36	Cerebral palsy	MC	Phenol	110	1	110	1	90	1	90	1
				Alcohol	95	1	140	0	120	1	120	1
5	4.81	Cerebral palsy	OB	Phenol	45	2	60	1	50	1	50	2
				Alcohol	60	1.5	70	1	60	1	60	1.5
6	10.72	Cerebral palsy	OB	Phenol	15	1	25	0	25	0	25	0
				Alcohol	10	1	20	0	20	0	20	0

OB: obturator nerves; MC: musculocutaneous nerves; PROM: passive range of movement; MAS: Modified Ashworth Scale

statistically significant (p=0.023). PROM was found to have no statistically significant difference compared to pre-treatment at three months (p=0.630) and six months (p=0.317) post injection.

Analysis of Obturator Neurolysis

The analysis was performed with the pair of musculocutaneous nerves exclude to study the effectiveness of phenol and alcohol neurolysis of obturator nerves for hip adductor spasticity (Table 3).

Phenol injection was found to be effective in PROM gain at one month (p=0.034), but no significant difference at three months (p=0.102) and six months (p=0.102). Tone reduction with significant MAS difference was found at one month (p=0.034), but not at three months (p=0.059) and six months (p=0.317).

Alcohol injection was also found to be effective in PROM gain at one month (p=0.034), but no significant difference at three months (p=0.317) and six months (p=0.317). Tone reduction with significant MAS difference was found at one month (p=0.038), but not at three months (p=0.063) and six months (p=0.317).

Comparison Between Phenol and Alcohol Groups

Table 4 shows the one month post treatment change in PROM and MAS among phenol and alcohol groups. There was no significant difference between phenol and alcohol groups with regards to PROM gain (p=0.849) and MAS reduction (p=0.847) at one month post treatment for all pairs, as well as obturator nerves only (PROM gain: p=0.180

Table 2 Outcome of phenol and alcohol neurolysis at various time-points (all subjects included)

		Median [Q1, Q3]				
Outcome	**Group**	**Pre-treatment**	**One month**	**Three months**	**Six months**	**p value***
PROM	Phenol	30º [13.75, 61.25]	40º [23.75, 72.5]†	30º [22.5, 60]	30º [22.5, 60]	0.011
PROM	Alcohol	30º [13.75, 68.75]	40º [20, 87.5]†	30º [18.75, 75]	30º [18.75, 75]	0.002
MAS	Phenol	2 [1, 2.25]	1 [0.75, 1.625]†	1.25 [0.75, 2]	2 [0.75, 2.25]	0.010
MAS	Alcohol	1.75 [1, 2.25]	1 [0, 1.625]†	1.25 [0.75, 2]	1.75 [0.75, 2.25]	0.004

*Friedman test; †p value <0.05 when comparing with pre-treatment using Wilcoxon's sign rank test.

Q1-first quartile; Q3-third quartile; PROM: passive range of movement; MAS: Modified Ashworth Scale

Table 3 Outcome of phenol and alcohol obturator neurolysis at various time-points

		Median [Q1, Q3]				
Outcome	**Group**	**Pre-treatment**	**One month**	**Three months**	**Six months**	**p value***
PROM	Phenol	30º [12.5, 37.5]	40º [22.5, 50]†	30º [20, 40]	30º [20, 40]	0.007
PROM	Alcohol	30º [12.5, 45]	40º [20, 55]†	30º [17.5, 45]	30º [17.5, 45]	0.008
MAS	Phenol	2 [1.5, 2.5]	1 [0.5, 1.75]†	1.5 [0.5, 2]	2 [1, 2.5]	0.010
MAS	Alcohol	2 [1.25, 2.5]	1 [0.5, 1.75]†	1.5 [0.5, 2]	2 [0.75, 2.5]	0.010

*Friedman test; †p value <0.05 when comparing with pre-treatment using Wilcoxon's sign rank test.

Q1-first quartile; Q3-third quartile; PROM: passive range of movement; MAS: Modified Ashworth Scale

Table 4 Comparison of outcome between phenol and alcohol neurolysis

			Median improvement [Q1, Q3]		
Outcome	**Nerves**	**No. of pairs**	**Phenol**	**Alcohol**	**p value***
PROM	All	6	10º [7.5, 11.25]	10º [8.75, 18.75]	0.849
PROM	Obturator neurolysis only	5	10º [10, 12.5]	10º [7.5, 10]	0.180
MAS	All	6	-1 [-1, -0.375]	-1 [-1, -0.5]	0.847
MAS	Obturator neurolysis only	5	-1 [-1, -0.75]	-1 [-1, -0.5]	0.513

*Mann-Whitney U test

Q1-first quartile; Q3-third quartile; PROM: passive range of movement; MAS: Modified Ashworth Scale

and tone reduction: p=0.513). No significant complication was reported in both phenol and alcohol groups.

Discussion

This is a pilot study evaluating the effect of phenol and alcohol neurolysis in the treatment of spasticity for paediatric patients. To our knowledge our study is the first study that compares the two treatments in Paediatric patients. Phenol nerve blocks have been used for treatment of spasticity for long time. Khalili and Betts introduced the use of phenol nerve block for spasticity fifty years ago.[11] Alcohol nerve block is also found to be effective in treating spasticity later.[11-16] For children, Spira[6] and Yadav[7] demonstrated phenol nerve block to be effective for management of spasticity in cerebral palsied children.

In the present study, we found that both phenol and alcohol are effective treatment for spasticity in children. The effect was observed to last less than 3 months. Action of phenol was reported to last from one month to 36 months and alcohol from two weeks to 36 weeks.[17] Previous paediatric studies reported the duration of phenol nerve block to be variable, ranging from three to 29 months.[6,7] With regeneration of the neuromuscular junction, the effects of phenol and alcohol wear off. Factors influencing the onset and duration of action include concentration of the medication, duration of exposure, method of delivery, and history of prior injections.[1] Table 5 summarises the responses to obturator nerve blocks in various studies employing different dosages in subjects with variable demographics and underlying severity. While the tone reduction effect tends to reduce with time in all studies, a higher dosage is associated with longer duration of sustained response. The relatively short-lasting effect in the present study may be related to the use of a lower dose of neurolytic agent. Moreover, the maximum median gain in hip PROM was only 10 degrees (from 30 to 40 degrees) one month post-injection; this reflects the severity of the underlying adductor spasticity and possible soft tissue contracture, rendering the chemodenervation effect relatively short-lived in the group of patients recruited.

We also found that there was no significant difference between phenol and alcohol treatment. A randomised controlled study comparing 5% phenol and 50% alcohol neurolysis of tibial nerve motor branches to the gastrocnemius muscle by Kocabas also suggested that both drugs are effective in reducing spasticity and the two treatments have no significant difference.[8] As currently there is a world-wide shortage of supply in phenol as nerve blocking agent, alcohol can be used as an alternative for neurolysis in paediatric patients with comparative tone reduction effect.

Matched samples were used in our study, with the two treatments given to the two limbs of the patients recruited. Patients recruited all suffered from significant spasticity affected both sides of the limbs. This can minimise the confounding factors due to differences in baseline characteristics between the two treatment groups.

No significant complications such as local reaction and infection over injection sites were observed in all patients in this study. However, complications of chemical neurolysis such as pain and disturbance to sensation are difficult to assess in our patients. Previous studies suggested that phenol and alcohol are safe with uncommon side effects.[4,16]

Adductor muscle spasticity and elbow flexor spasticity are common among cerebral palsied children with poor gross motor function. These can cause much pain, distress and difficulties in daily routine care. Chemical neurolysis with phenol or alcohol is one of therapeutic possibilities

Table 5 Comparison of responses following obturator nerve blocks in different studies

Studies	Age (years)	No. of obturator blocks	Dose (ml)	Baseline findings	Response
Leung et al*	8.15 (3.96-16.35)	12	0.5-1	Hip abduction (R/L): 30º/30º MAS (R/L): 2/2	Best response at 1 month 40º/40º MAS1/1; returned to baseline by 6 months
Spira et al[6]	2 to over 8	38	2-5	Severe in 11 cases preventing oriental sitting	Good relief in 74% (48 hours); 68% (3 weeks); 52% (3-6 months)
Lam et al[3]	78.1±12.9	32	5	Hip abduction (R/L): 40º/47º MAS(R/L): 3.2/3.0	MAS reduction ≥1 in 75% (6 weeks, MAS 1.3/1.5); 69% (6 months, MAS 1.9/2.0); 54% (9 months, MAS 2.1/2.0)

*Current study

to manage spasticity. The major advantages of chemical neurolysis include low cost of the drugs, rapid onset of action and potency for large muscle groups like hip adductors.[5]

Limitations

The number of subjects included in this study is small. The number of subjects recruited in this study was actually limited by the unstable availability of phenol. Only one pair of musculocutaneous nerve was included in this study and only one case received alcohol injection with 75% concentration. A larger sample size is necessary for further studies to analyse an optimal drug concentration, the lowest effective dose and for subgroup analysis. The therapeutic effect, duration of action and safety of higher concentration of alcohol at 75-100% has yet been explored. More outcomes can be assessed in future studies such as hygiene score and pain score. Side effects of treatment may be under-reported because majority of our patients were unable to communicate the pain and sensory complications.

Conclusion

This study showed that obturator and musculocutaneous neurolysis with 5% phenol or 50-75% alcohol is an effective treatment to reduce spasticity in children with chronic neurological disease. This procedure can be introduced to this group of patients earlier to prevent complications of spasticity and improve their quality of life. As a nerve blocking agent, alcohol is a safe and effective alternative to replace phenol in paediatric patients.

Acknowledgements

The authors thank all the clinical staff and patients who took part in this study, in particular Miss Ellen Yu, statistician from Princess Margaret Hospital for her assistance in statistical analysis.

Declaration of Interests

None

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Appendix 1

Modified Ashworth Scale[18]

Scoring:

0 No increase in muscle tone
1 Slight increase in muscle tone, manifested by a catch and release or by minimal resistance at the end of the range of motion when the affected part(s) is moved in flexion or extension
1+ Slight increase in muscle tone, manifested by a catch, followed by minimal resistance throughout the remainder (less than half) of the ROM
(MAS score 1+ is treated as 1.5 for statistical analysis in this study)
2 More marked increase in muscle tone through most of the ROM, but affected part(s) easily moved
3 Considerable increase in muscle tone, passive movement difficult
4 Affected part(s) rigid in flexion or extension