Technology Assessment for Management of Congenital Diaphragmatic Hernia : Immediate *versus* Delayed Surgery

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Abstract

Background : Congenital diaphragmatic hernia (CDH) is one of the high-risk diseases in pediatric surgery, especially in neonates with symptom presentation within 6 hours after birth. Opinion regarding the time of surgery has gradually shifted from immediate repair to a policy of stabilization and delayed repair. Whether delayed surgery is beneficial remains controversial.

Objective : To evaluate the outcomes regarding whether delayed surgical repair improves survival in CDH neonates, who are symptomatic immediately after delivery, is more beneficial than immediate surgery.

Material and Method : Data were obtained by searching MEDLINE (1966-2002) and the Cochrane Database, Issue 2, 2003 using the term "congenital diaphragmatic hernia" and "surgery". Inclusion criteria were randomized controlled trial (RCT), prospective trial (PT), retrospective analysis (RA) and meta-analysis (MA). Information from the literature was analyzed by the computer program of Epi Info Version 3. Statistical significance was reliable at the level of $p < 0.05$.

Results : Twenty-five studies were obtained and RCT : RA was 2 : 23. Analysis of results of CDH management revealed that pre-operative stabilization and delayed surgery improved the survival rate in 14 of 25 in the literature ($p < 0.05$), while the remaining 11 articles showed no statistical difference of survival between immediate and delayed surgery ($p > 0.05$).

Conclusion : From the evidence-based analysis, the results of CDH management between immediate *versus* delayed surgery were unclear. From the reviewer's experience at the Queen Sirikit National Institute of Child Health, the strategy of pre-operative stabilization and delayed surgery had better improved survival of CDH than immediate surgery.

Key word : Congenital Diaphragmatic Hernia, Immediate Surgery, Delayed Surgery

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J Med Assoc Thai 2003; 86 (Suppl 3): S727-S733

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Congenital diaphragmatic hernia (CDH) occurs in approximately 1 : 5,000 livebirths and was generally considered a fatal condition through the early 20th century especially in patients with clinical presentation shortly after birth. Despite many advances in the medical and surgical care of patients, the mortality for this condition remains quite high.

In 1940-1946, Ladd and Gross[1,2] demonstrated that surgical repair of CDH could be successfully undertaken in an infant. Their earliest reports were encouraging, demonstrating a marked improvement in survival compared to the previous approach of watchful waiting. They justified urgent surgery by noting that these infants had a large amount of gas in the bowel and thorax, which was thought to cause lung compression and respiratory distress resulting in the need for urgent correction. A policy of emergency or immediate surgical repair has persisted since then, but the survival rate (SR) of this condition is still 40 per cent - 70 per cent[3,4].

However, surgery has been shown to be associated with deterioration in lung compliance, which may be improved by stabilization prior to surgery. The first recommendation of pre-operative stabilization and delayed surgery was advocated by Cartlidge et al [5] in 1986 when the survival rate of their patients changed from 12.5 per cent (immediate repair) to 52.9 per cent (delayed repair). Many pediatric surgeons are currently employing a strategy of delay for some period of time prior to correction of the defect in order to achieve a minimal level of ventilator support, to document the absence of pulmonary hypertension, to show improvement in pulmonary compliance, or to show that the lung radiographic appearance is improved prior to repair. On the contrary, survival rate of the CDH patients has not improved as the suspected goal in some institutes, eventhough surgeons have been treating these patients along the policy of pre-operative stabilization and delayed surgery. So, assessment of CDH management outcomes should be performed to evaluate the difference between immediate *versus* delayed surgery.

Objective

The objective of this review was to summarize the available data for evaluation of the management outcomes of CDH neonates who are symptomatic immediately after delivery. Information data was analysed whether pre-operative stabilization and delayed surgery improves the CDH survival rather than immediate surgical repair.

MATERIAL AND METHOD

Searching for evidence-based information data was performed by the standard method of conducting a systematic review. The Cochrane Database of Systematic Review, Issue 2, 2003 and MEDLINE (1966-2002) were searched using the search terms "congenital diaphragmatic hernia" and "surgery". Reference lists for each identified article were reviewed to locate other potentially relevant articles. Criteria for collection of the articles were : 1. Randomized controlled trial, (RCT), prospective trials (PT), retrospective analysis (RA), and meta-analysis (MA), 2. Study about outcomes of CDH patients with presenting symptoms shortly after birth and unlimited number of patients in each article.

The inclusion articles were assessed for results of CDH management and compared with the different outcomes between immediate and delayed surgery. The survival rate of other procedures were tested for the difference of statistical significance by the computer program Epi Info, Version 3 at the level of $p < 0.05$.

RESULTS

Twenty-five studies were identified, only two were randomized controlled trials and the remaining 23 were retrospective analysis. Outcomes of CDH management were categorized in 2 groups.

The first group of the studies indicated that pre-operative stabilization and delayed surgery obtained a higher survival rate of CDH management than immediate surgery (Table 1)[5-18]. Notice from this study, delayed surgery was used for CDH treatment by Mc Namara et al[6] more than 30 years ago.

The second group of studies indicated that the survival rate of CDH management was not different between immediate and delayed surgery (Table 2)[19-29].

Changing of concept from immediate to delayed surgery is only one of the important factors for CDH management. Alternative ventilatory strategies such as permissive hypercapnia, inhaled nitric oxide (iNO) with high frequency oscillatory ventilation (HFOV), extracorporeal membrane oxygenation (ECMO) have been used in an effort to stabilize these infants prior to surgery or as rescue therapy following surgery. Kays et al[30] reported their experience in

Table 1. Delayed surgery obtained a higher survival rate than immediate surgery.

Authors/Years/Interventions	Designs	Immediate Surgery		Delayed Surgery		P-value
		No.	SR (%)	No.	SR (%)	
1. Mc Namara[6] / 1968 / CMV	RA	52	54	142	80	< 0.01
2. Wiener[7] / 1982 / ECMO	RA	66	42	93	59	0.04
3. Cartlidge[5] / 1986 / CMV	RA	16	12.5	17	52.9	0.01
4. Breaux[8] / 1991 / ECMO	RA	15	20	20	55	0.04
5. Charlton[9] / 1991 / ECMO	RA	-	-	68	70.9	-
6. Nakayama[10] / 1991 / ECMO	RA	13	46.2	9	88.9	< 0.01
7. West[11] / 1992 / ECMO	RA	65	43	45	81.8	< 0.01
8. Miguet[12] / 1994 / HFOV	RA	-	-	18	72.2	-
9. Adolph[13] / 1995 / ECMO	RA	-	-	18	83	-
10. Wung[14] / 1995 / ECMO	RA	17	82	18	94	0.03
11. Reickert[15] / 1996 / ECMO	RA	66	56	33	79	0.03
12. Wilson[16] / 1997 / ECMO	RA	70	42.8	126	58.7	0.03
13. Frenckner[17] / 1997 / ECMO	RA	-	-	48	91	-
14. Reys[18] / 1998 / HFOV + iNO	RA	-	-	22	81	-

CMV = conventional mechanical ventilation, ECMO = extracorporeal membrane oxygenation,
HFOV = high frequency oscillatory ventilation, iNO = inhaled nitric oxide, RA = retrospective analysis

Table 2. Immediate and delayed surgery obtained no difference of survival rate.

Authors/Years/Interventions	Designs*	Immediate Surgery		Delayed Surgery		P-value
		No.	SR (%)	No.	SR (%)	
1. Langer[19] / 1988 / HFOV	RA	31	42	30	50	0.53
2. Hazebrock[20] / 1988 / CMV	RA	-	-	13	39	-
3. Shanbhogue[21] / 1990 / CMV	RA	26	54	23	48	0.07
4. Wilson[22] / 1992 / ECMO	RA	55	43	46	45	0.84
5. Goh[23] / 1992 / CMV	RA	-	-	67	67	-
6. Coughlin[24] / 1993 / ECMO	RA	19	42	13	46.2	0.82
7. Nio[25] / 1994 / ECMO	RCT	12	75	18	72	0.60
8. Lessin[26] / 1995 / ECMO	RA	91	38.5	32	39	0.92
9. de la Hunt[27] / 1996 / ECMO	RCT	26	46	28	57	0.42
10. Azarow[28] / 1997 / HFOV, ECMO	RA	111	53	122	56.6	0.60
11. Kamata[29] / 1998 / HFOV	RA	23	78.3	18	38.9	0.01

HFOV = high frequency oscillatory ventilation, CMV = conventional mechanical ventilation,
ECMO = extracorporeal membrane oxygenation, RA = retrospective analysis, RCT = randomized controlled trial

89 CDH patients and showed strategic changing into 3 eras. Results of treatment indicated that pre-operative stabilization with permissive hypercapnia and delayed surgery decreased the incidence of pneumothorax and improved the survival rate in the third era (Table 3). In 1997, two studies from Boston[16] and Toronto[28] showing the outcome of various strategies of CDH treatment during different eras were published. Treatments of both series were managed at the same time. Outcomes of immediate surgery, hyperventilation and alkalosis comparison with delayed surgery and permissive hypercapnia showed that delayed surgery had a higher survival rate than immediate surgery with statistical significance in the Boston experience (Table 1) and no statistical significance in the Toronto experience (Table 2).

Results of treatment in high-risk CDH patients at the Queen Sirikit National Institute of Child Health revealed that pre-operative stabilization and delayed surgery obtained better survival than immediate surgery with a statistical difference (Table 4)[31]. From the reviewer's observation, low pre-operative death and high post-operative death were noted in CDH with immediate surgery, while high pre-operative death and low post-operative death were noted in CDH with delayed surgery (Table 5). Clark et al[32] reported a

Table 3. Results of CDH treatment by Kays et al[30] between 1983-1992 (n = 89).

Eras	Strategies	Results		
		No.	Survival	%
1. December 1983 - May 1988	Paralysis, hyperventilation, alkalinization, PaO_2 200-300 mmHg, immediate surgery (< 24 hours).	13	2	15
2. June 1988 - July 1992	Paralysis, hyperventilation, alkalinization, ECMO, PaO_2 > 100 mmHg, delayed surgery > 24 hours.	16	7	44
3. August 1992	Sedation, permissive hypercapnia, PaCO2 40-60 mmHg, PaO_2 80-100 mmHg, O_2 saturation > 97%, using iNO or ECMO if preductal O_2 saturation < 85%, post ductal PaO2 30 mmHg, delayed surgery > 24 hours.	60	47	78

Table 4. Results of treatment of high-risk CDH at the Queen Sirikit National Institute of Child Health between 1992-2001 (n = 136).

Years	Surgical strategies	Total No. cases	Survival	
			cases	%
1992-1994	Immediate surgery (within 6 hours)	44	12	27.3
1995-1997	Urgent surgery (± 24 hours)	48	12	25
1998-2001	Delayed surgery (1-7 days)	44	26	59.1

Table 5. Comparison of pre-operative and post-operative death between immediate and delayed surgery.

Authors	Years	Designs*	Immediate Surgery		Delayed Surgery	
			Pre-op. death (%)	Post-op. death (%)	Pre-op. death (%)	Post-op. death (%)
1. Nakayama DK[10]	1991	RA	0	54	11	0
2. Reickert CA[14]	1996	RA	13.5	35	21	0
3. Azarow K[27]	1997	RA	10	38	35	10
4. Kamata S[28]	1998	RA	0	22	61	0
5. Niramis R[31]	2003	RA	0	73	29.5	13

* Designs : RA = retrospective analysis

meta-analysis of CDH treatment of 62 tertiary hospitals from Europe, Australia and USA, and the results showed patients' death during stabilization in about 15 per cent and post-operative death in about 28.5 per cent.

Moyer et al[33] from the Cochrane Database of Systematic Review studied late *versus* early surgical correction for CDH by collection of randomized controlled trials. Only 2 articles of RCT (Nio et al[25] and de la Hunt et al[27]) were available for analysis. The results of both trials revealed no statistical difference in survival rate between immediate and delayed surgery (Table 2).

DICUSSION

Assessment of the 2 RCT and the 23 retrospective analysis was analyzed. Fourteen articles of retrospective analysis revealed an improvement in the survival rate by pre-operative stabilization and delayed surgery (Table 1). Most of the 14 articles used a historical survival rate of immediate surgery for the control group[5-8,10,11,14-16]. The remaining 5 articles did not mention the results of immediate surgery[9,12,13,17,18].

Eleven articles (2 RCT, 9 RA) suggested that there was no statistically significant difference between the survival rate of immediate and delayed

surgery. Two of the 11 articles did not mention the historical survival rate of immediate surgery(20,23).

The authors who preferred CDH treatment with late surgery suggested pre-operative stabilization should be performed until physiological changes occur, such as improved pulmonary compliance, decreased pulmonary hypertension, or others. With this approach, operation would be delayed for days or weeks as necessary. Delayed surgery is the only important strategy for survival and the addition of developing ventilatory support should be the most important factor for improvement of survival in CDH patients.

SUMMARY

The comparison of survival rate in CDH patients revealed controversial results, increased survival with delayed surgery in 14 articles and no difference in survival between immediate and delayed surgery in 11 articles. However, the reviewer's experience at the Queen Sirikit National Institute of Child Health suggested that pre-operative stabilization and delayed surgery should be the appropiate strategy for the management of high-risk CDH infants because of the obvious increased survival rate.

ACKNOWLEDGEMENT

The author wishes to thank Dr. Surapee Ruangsuwan, Director of the Queen Sirikit National Institute of Child Health for permission to publish this article. The author also wishes to thank the members of the Congenital Diaphragmatic Hernia Study Group at the Queen Sirikit National Institute of Child Health for their excellent co-operation in the technology assessment.

(Received for publication on August 30, 2003)

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ประเมินเทคโนโลยีในการรักษาโรคไส้เลื่อนกะบังลมแต่กำเนิด : การผ่าตัดเร่งด่วนกับการผ่าตัดที่ชะลอนานออกไป

*รังสรรค์ นิรามิษ, พบ**

เบื้องหลัง : ไส้เลื่อนกะบังลมแต่กำเนิดเป็นโรคที่มีความเสี่ยงสูงโรคหนึ่ง โดยเฉพาะอย่างยิ่ง ในเด็กทารกที่มีอาการภายใน 6 ชั่วโมงแรกหลังคลอด ความเห็นในเรื่องเวลาของการผ่าตัดโรคนี้ได้เปลี่ยนแนวคิดจากการผ่าตัดแบบเร่งด่วนไปเป็นการรักษาแบบประคับประคองระยะหนึ่ง จนผู้ป่วยดีขึ้นแล้วนำไปผ่าตัด การผ่าตัดที่ชะลอนานออกไปมีผลการรักษาดีกว่าผ่าตัดเร่งด่วน จริงหรือไม่ ยังมีความคิดเห็นที่ขัดแย้งกันอยู่

วัตถุประสงค์ : เพื่อประเมินผลการผ่าตัดที่ชะลอนานออกไปเกิน 24 ชั่วโมงหลังคลอด จะได้ผลทำให้ผู้ป่วยรอดชีวิตสูงกว่าการผ่าตัดเร่งด่วนในผู้ป่วยไส้เลื่อนกะบังลมแต่กำเนิดที่มีอาการเกิดขึ้นเร็วหลังคลอด

วัสดุและวิธีการ : ข้อมูลของการศึกษาได้จากการค้นหาใน MEDLINE (1966–2002), Cochrane Database, Issue 2, 2003 ใช้เทอมที่ค้นคือ "ไส้เลื่อนกะบังลมแต่กำเนิด" และ "การผ่าตัด" ข้อมูลที่คัดเลือกได้จากวรรณกรรมประเภท การศึกษาไปข้างหน้าที่มีกลุ่มเปรียบเทียบ (randomized controlled trial) การศึกษาไปข้างหน้าที่ไม่มีกลุ่มเปรียบเทียบ (prospective trial) การศึกษาวิเคราะห์ข้อมูลย้อนหลัง (retrospective analysis) และจากการวิเคราะห์ข้อมูลจากวรรณกรรมหลายฉบับมารวมกัน (meta-analysis) ข้อมูลจากวรรณกรรมที่ได้คัดเลือกมา นำไปวิเคราะห์ด้วยโปรแกรมคอมพิวเตอร์ Epi Info Version 3 หาค่าความแตกต่างทางสถิติที่ระดับความเชื่อมั่นร้อยละ 95

ผล : มีรายงานที่ศึกษาเกี่ยวกับเรื่องการผ่าตัดเร็วหรือช้าในโรคนี้ที่ค้นได้ 25 รายงาน เป็นชนิดศึกษาไปข้างหน้ามีกลุ่มเปรียบเทียบ : การศึกษาวิเคราะห์ย้อนหลังเท่ากับ 2 : 23 วิเคราะห์ผลของการรักษาโรคไส้เลื่อนกะบังลม พบว่า 14 ใน 15 รายงาน สรุปว่าการรักษาแบบชะลอการผ่าตัดประคับประคองให้ผู้ป่วยดีขึ้นมีความคงที่ในเรื่องของระบบทางเดินหายใจและระบบไหลเวียนของโลหิต แล้วจึงนำไปผ่าตัด ช่วยให้อัตราการรอดชีวิตดีขึ้น ($p < 0.05$) ในขณะที่ 11 ใน 25 รายงาน สรุปว่าไม่มีความแตกต่างกันระหว่างการผ่าตัดเร่งด่วนและการผ่าตัดช้า ($p > 0.05$)

สรุป : ข้อมูลหลักฐานของการศึกษาจากต่างประเทศที่นำมาวิเคราะห์พบว่ายังไม่มีการยืนยัน ที่เด่นชัดในผลของการรักษาที่จะสรุปว่าการผ่าตัดเร็วและการผ่าตัดช้ามีความแตกต่างกันอย่างไร ประสบการณ์ในสถาบันสุขภาพเด็กแห่งชาติมหาราชินี พบว่าการรักษาชนิดชะลอการผ่าตัด ให้นานออกไปและแก้ไขให้ผู้ป่วยดีขึ้นจนมีความคงที่ทางสรีรวิทยาแล้วนำไปผ่าตัด มีผลการรักษาดีกว่าคืออัตราการรอดชีวิตของผู้ป่วยสูงกว่าการรักษาแบบผ่าตัดเร่งด่วน

คำสำคัญ : ไส้เลื่อนกะบังลมแต่กำเนิด, การผ่าตัดเร่งด่วน, การผ่าตัดที่ชะลอนานออกไป

รังสรรค์ นิรามิษ
จดหมายเหตุทางแพทย์ ฯ 2546; 86 (ฉบับพิเศษ 3): S727–S733

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