

Centro Studi EBN, Università di Bologna, Azienda Ospedaliero-Universitaria di Bologna, CeVEAS
Master EBP e Metodologia della ricerca clinico-assistenziale

15.10.08

GRADE

sintesi dei risultati delle prove di efficacia

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CeVEAS

Summary of findings				
No of patients		Effect		Quality
active management of the third stage of labour	control	Relative (95% CI)	Absolute	
Blood loss =>1000 ml				
27/3126	83/3158	RR 0.33 (0.21 to 0.51)	17 fewer per 1000 (from 13 fewer to 21 fewer)	⊕○○○ VERY LOW
	1.5%		10 fewer per 1,000	
	3.2%		21 fewer per 1,000	

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GRADE evidence profile table

Quality assessment						Summary of findings					
						No of patients		Effect			Quality
No of studies (Ref)	Design	Limitations	Consistency	Directness	Other considerations	Intervention	Control	Baseline risk (without treatment) (95%CI)	Relative risk (95%CI)	NNT/NNH (95%CI)	
Benefits:											
Outcome											
Harms:											
Outcome											

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GRADE summary of findings

Summary of findings					
	Intervention	Control	Baseline risk (without treatment) (95%CI)	Relative risk (95%CI)	NNT/NNH
Benefits:					
Outcome					
Harms:					
Outcome					

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GRADE Evidence Profile - QUESTION: Should active management of the third stage of labour be used [by skilled providers] for all women to prevent PPH?

Quality assessment							Summary of findings					
No of studies	Design	Limitations	Consistency	Directness	Other considerations	No of patients		Effect			Quality	Importance
						Active management	Standard procedures	Baseline Risk (95%CI)	Relative risk (95%CI)	NNT (95%CI)		
Benefits:												
Maternal deaths												
0	-	-	-	-	-	-	-	-	-	-	-	8.5
Admission to intensive care unit												
0	-	-	-	-	-	-	-	-	-	-	-	6.4
Blood loss ≥ 500 ml												
4 PW 00 ¹ Ad 97 Br 88 Du 90 Hi 98	RCT	serious limitation ^{2,3,17} -1	no important inconsistency	some uncertainty about directness ^{4,5} -1	none	3126	3158	min 8.3% (6.3, 10.3) max 17.9% (15.3, 20.5)	0.38 (0.32, 0.46)	min 8 (6.7, 11.2) max 16 (11.7, 24.7)	low quality ++oo	6.3
Blood loss ≥ 1000 ml												
4 PW 00 ¹ Ad 97 Br 88 Du 90 Hi 98	RCT	serious limitation ^{2,3,17} -1	no important inconsistency	some uncertainty about directness ^{4,5} -1	none	3126	3158	min 1.5% (0.6, 2.1) max 3.2% (2.0-4.4)	0.33 (0.21, 0.51)	min 41 (26.5, 90.1) max 73 (43.3, 225.5)	low quality ++oo	7.7
Need for blood transfusion												
5 PW 00 ¹ Ad 97 Br 93 Fr 88 Du 90 Hi 98	RCT	minor limitation ^{3,4}	no important inconsistency	some uncertainty about directness ⁷ -1	none	3229	3248	5.7% (4.1-7.2) ¹⁶	0.34 (0.22, 0.53)	28 (18.7, 59.1) ¹⁶	moderate quality +++o	7.8

GRADE Evidence Profile - QUESTION: Should active management of the third stage of labour be used [by skilled providers] for all women to prevent PPH?

Quality assessment							Summary of findings					
No of studies	Design	Limitations	Consistency	Directness	Other considerations	No of patients		Effect			Quality	Importance
						Active management	Standard procedures	Baseline Risk (95%CI)	Relative risk (95%CI)	NNT (95%CI)		
Harms												
Side effect requiring treatment												
1 PW 00 ¹ Hi 98	RCT	minor limitation ³	one trial only	some uncertainty about directness ¹⁵ -1	none	716	731	28% (24.8, 31.3)	0.80 (0.49, 0.74)	-9 (-14.5, -6.5)	moderate quality +++o	6.2
Manual removal of placenta												
5 PW 00 ¹ Ad 97 Br 93 Fr 88 Du 90 Hi 98	RCT	serious limitation ^{3,17} -2	major inconsistency ¹⁸ 1	some uncertainty about directness ^{4,5} -1	imprecise and sparse data -1	3229	3248	min 0.14% (-0.13, 0.41) max 2.59% (1.53, 3.66)	1.21 (0.82, 1.78)	min NS max 39 (26.4, 75.2)	very low quality oooo	6.2
Nausea												
3 PW 00 ¹ Br 88 Du 90 Hi 98	RCT	serious limitation ^{3,17} -2	no important inconsistency	some uncertainty about directness ^{4,10} -1	none	1680	1727	min 8.77% (3.56, 13.99) max 11.50% (8.21, 13.78)	1.83 (1.51, 2.23)	min 7 (4.0, 24.4) max 18 (11.8, 36.0)	very low quality +ooo	4.0
Vomiting												
3 PW 00 ¹ Br 88 Du 90 Hi 98	RCT	serious limitation ^{3,17} -2	no important inconsistency	some uncertainty about directness ^{4,10} -1	none	1680	1727	min 1.75 (-0.87, 4.18) max 6.48 (4.82, 8.13)	2.19 (1.68, 2.86)	min 10 (5.8, 37.9) max 18 (12.0, 35.4)	very low quality +ooo	4.7

GRADE summary of findings

Summary of findings				
Intervention	Control	Baseline risk (without treatment) (95%CI)	Relative risk (95%CI)	NNT/NNH
Benefits:				
Outcome				
Harms:				
Outcome				

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GRADE summary of findings

Summary of findings				
	Intervention	Control		
Benefits:				
Outcome				
Harms:				
Outcome				

Number of patients with an event/outcome of interest and total number of patients treated (denominator)

In the two groups compared

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GRADE summary of findings: benefits

Quality assessment		Summary of findings					
No of studies (Ref)		No of patients					
		Active management	Standard procedures				
Benefits:							
Maternal deaths							
0		-	-				
Admission to intensive care unit							
0		-	-				
Blood loss ≥ 500 ml							
4	PW 00 ¹ Ad 97 Br 88 Du 90 Hi 98	3126	3158				
Blood loss ≥ 1000 ml							
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GRADE summary of findings

Summary of findings				Baseline risk (without treatment) (95%CI)		
	Intervention	Control				
Benefits:						
Outcome						
Harms:						
Outcome						

It is the number of events (event rate) in the control groups

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GRADE summary of findings: benefits

Quality assessment		Summary of findings						
No of studies (Ref)		No of patients		Effect				
		Active management	Standard procedures	Baseline Risk (95%CI)				
Benefits:								
Maternal deaths								
0		-	-	-				
Admission to intensive care unit								
0		-	-	-				
Blood loss ≥ 500 ml								
4 PW 00 ¹ Ad 97 Br 88 Du 90 Hi 98		3126	3158	min 8.3% (6.3, 10.3) max 17.9% (15.3, 20.5)				
Blood loss ≥ 1000 ml								
4 PW 00 ¹ Ad 97 Br 88 Du 90 Hi 98		3126	3158	min 1.5% (0.6-2.4) max 3.2% (2.0-4.4)				

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GRADE summary of findings

Quality assessment		Summary of findings						
No of studies (Ref)	Intervention	No of patients		Effect				
		Active management	Standard procedures	Baseline Risk (95%CI)	Relative risk (95%CI)			
Benefits:								
Outcome								
Harms:								
Outcome								

Relative measure of effect and its confidence interval (precision of the estimate):

- Relative risk
- Odds ratio
- Hazard ratio

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GRADE summary of findings: benefits

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GRADE summary of findings

		Intervention		Relative risk (95%CI)		NNT/NNH (95%CI)	
Benefits:							
Outcome							
Harms:							
Outcome							

Absolute difference or magnitude of the effect that is the difference in absolute numbers between the baseline risk in the control and event rate in the treatment group:
Its reciprocal is the NNT or NNH that is the number needed to treat or to harm

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GRADE summary of findings: benefits

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GRADE summary of findings: harms

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