

# Prospective study to evaluate early Clauss fibrinogen and Fibtem® as predictors of major obstetric haemorrhage

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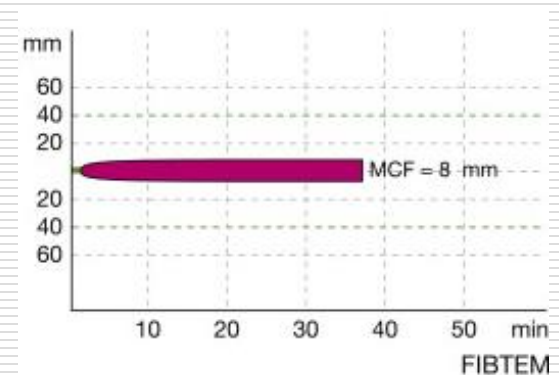
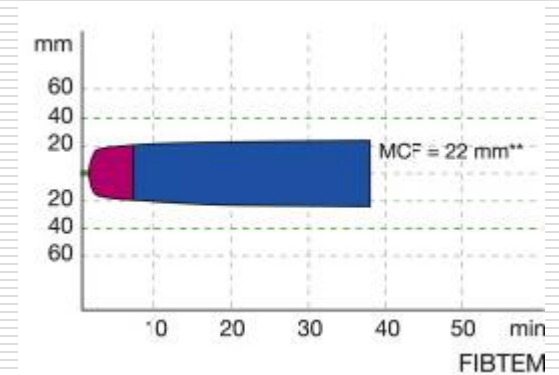


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# Background

- Normal fibrinogen level in pregnancy (4-6 g/L) differs from that in the non-pregnant population (2-3 g/L)
- Fibrinogen falls early in postpartum haemorrhage (PPH)<sup>1</sup>
- Fibrinogen observed to be predictive for need for transfusion and invasive procedures<sup>2</sup>
- Fibtem® provides near-patient assessment of fibrinogen function



1. De Lloyd L et al. Standard haemostatic tests following major obstetric haemorrhage. *Int J of obs anaes* 2011; 20(2):135-41  
2. Charbit B et al. The decrease of fibrinogen is an early predictor of the severity of postpartum hemorrhage. *J Thromb Haemost* 2007; 5(2):266-73

# Aims

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## Primary outcomes:

- ❑ To investigate prospectively whether early fibrinogen is predictive of progression to transfusion
- ❑ To investigate whether Fibtem® has the same predictive value

## Secondary outcomes:

- ❑ To investigate whether these biomarkers predict need for transfusion of 4 or more units
  - ❑ To establish a Fibtem® trigger at which to treat with fibrinogen for a randomised clinical trial
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# Methods

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- ❑ Research ethics committee approval and informed consent
  - ❑ Inclusion criteria: PPH  $\geq$  1000ml
  - ❑ Blood taken for fibrinogen and Fibtem®
  - ❑ All patients managed as per PPH protocol
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# Results

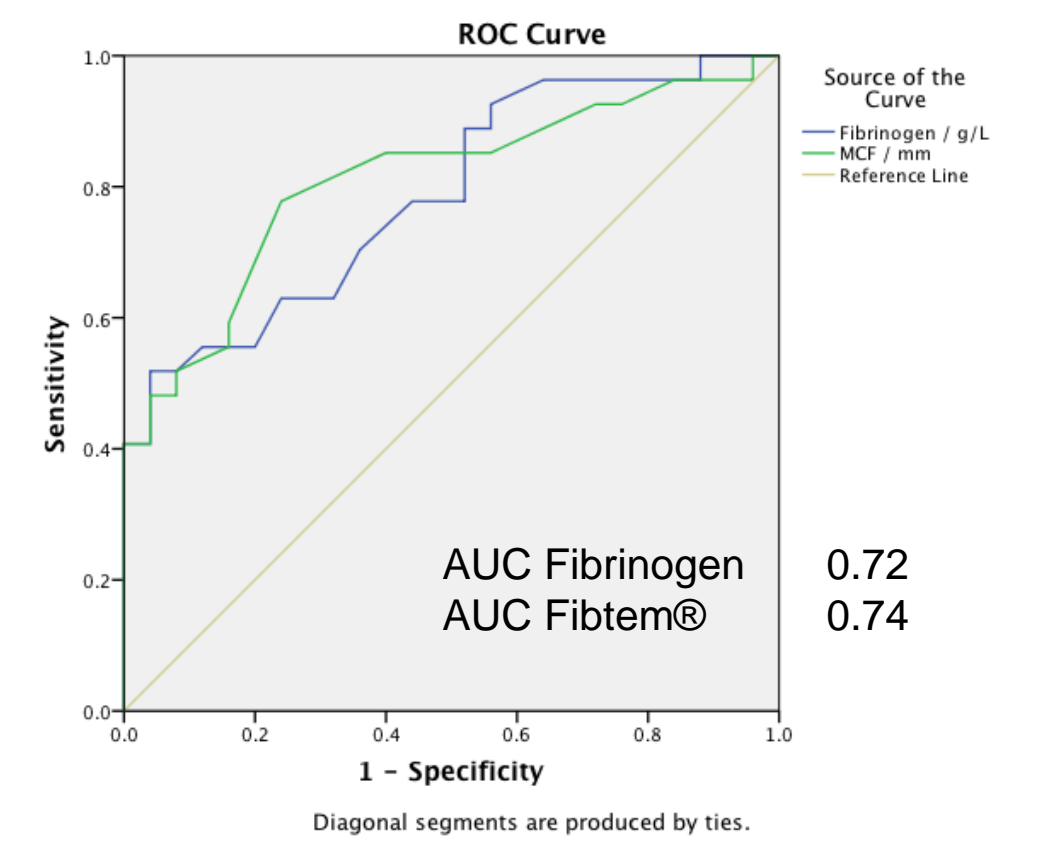
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- April to September 2012
- 179/3200 births were enrolled (5.6/100)

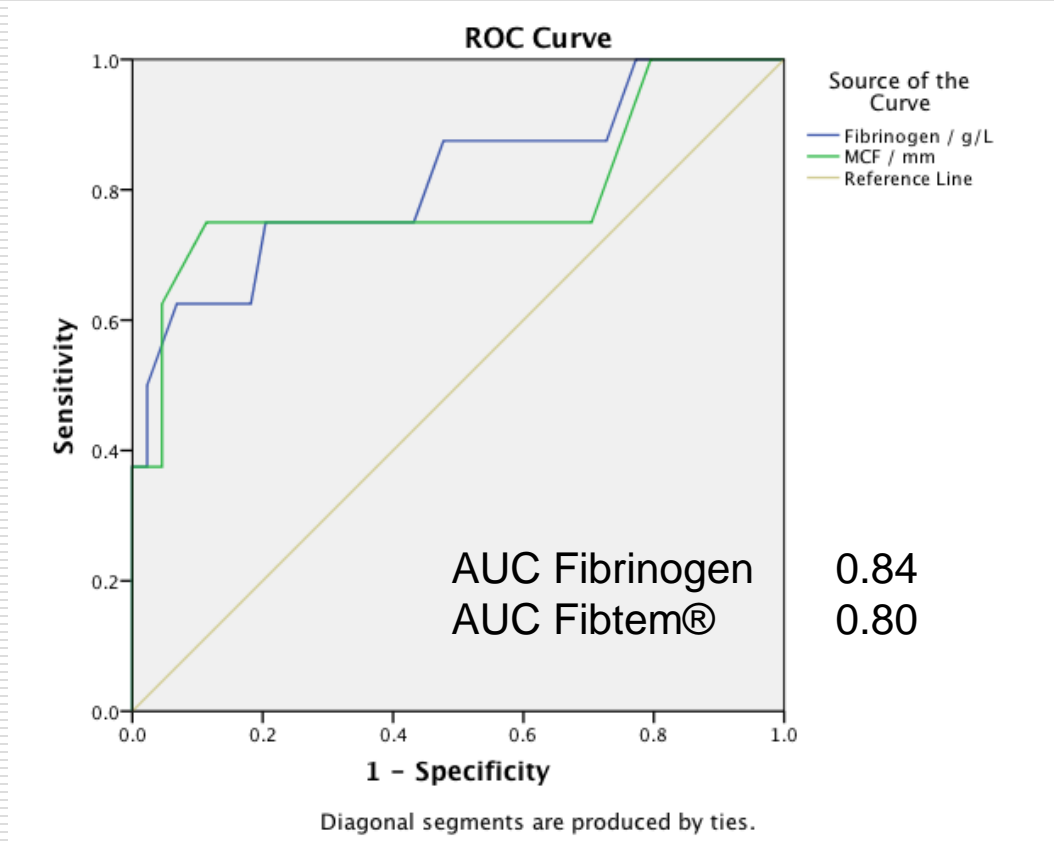
>2500ml	17/179 (9.5%)
RBC transfusion	42/179 (23.5%)
≥4 units RBC transfused	10 (5.6%)

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# ROC analysis - Progression to RBC transfusion



# ROC analysis - Progression to 4 units transfusion



## Progression to need for invasive procedures

AUC Fibrinogen	0.93
AUC FIBTEM®	0.89

# Results

<b>AUC</b> 95% CI <i><b>p value</b></i>	Any RBC transfusion	≥4 units RBC transfusion	Invasive procedures
Fibrinogen	<b>0.72</b>	<b>0.84</b>	<b>0.93</b>
	<i>0.67 – 0.91</i>	<i>0.68 – 0.99</i>	<i>0.69 – 1.00</i>
	<b>p&lt;0.01</b>	<b>p&lt;0.01</b>	<b>p&lt;0.01</b>
Fibtem® MCF	<b>0.74</b>	<b>0.80</b>	<b>0.89</b>
	<i>0.69 – 0.93</i>	<i>0.60 – 0.98</i>	<i>0.78 – 1.00</i>
	<b>p&lt;0.01</b>	<b>p&lt;0.01</b>	<b>p&lt;0.01</b>



# Results

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- Fibtem® MCF <18mm identifies need for any RBC transfusion with:
    - Positive predictive value 89% (95% CI 67-98)
    - Negative predictive value 84% (78-90)
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# Conclusion

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- Fibrinogen and Fibtem® predict the need for:
    - any RBC transfusion
    - $\geq 4$  units RBC
    - Invasive procedures
  - Fibtem® MCF  $< 18$ mm had a high PPV for need for transfusion
  - Fibtem® is available 20 minutes versus Clauss fibrinogen in 60 minutes
  - It is unknown whether early correction of fibrinogen or Fibtem in PPH improves outcome
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**Questions?**

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