New clinical data from the US

Placental alpha microglobulin-1 compared with fetal fibronectin to predict preterm delivery in symptomatic women (1)


Objective: A prospective U.S. multi-center trial conducted at 15 university and community hospitals comparing PartoSure and the Rapid fFN test* for the prediction of imminent spontaneous preterm delivery (sPTD) within 7 and 14 days from time of testing.

Study population: N: 635, GA: 24-34\textperthousand \textperthousand weeks

PartoSure Results:

≤ 7 Days: PPV: 23.1% | NPV: 99.5%
≤ 14 Days: PPV: 30.8% | NPV: 98.6%

Findings: In women with symptoms of preterm labor (PTL), the PPV for preterm delivery within 7 days was shown to be 5-fold higher for PartoSure compared to the detection of fFN.

Predictive performance of PAMG-1 vs fFN test for risk of spontaneous preterm birth in symptomatic women attending an emergency obstetric unit: retrospective cohort study (2)


Objective: Retrospective audit of two time periods, calendar years 2012 and 2016, to determine the effectiveness of the PartoSure vs the detection of QuikCheck fFN** in patients presenting to the hospital with signs and symptoms of PTL for prediction of delivery within 7 or 14 days from time of testing.

Study population: N: 745, GA: 24-34\textperthousand \textperthousand weeks

PartoSure Results:

≤ 7 Days: PPV: 35.3% | NPV: 98.3%
≤ 14 Days: PPV: 41.2% | NPV: 97.1%

*FDA-approved. **CE-marked.

Trusted results in Europe

<table>
<thead>
<tr>
<th>PPV</th>
<th>NPV</th>
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</thead>
<tbody>
<tr>
<td>PartoSure</td>
<td>Rapid fFN</td>
</tr>
<tr>
<td>≤ 7 Days</td>
<td>23.1%</td>
</tr>
<tr>
<td>≤ 14 Days</td>
<td>30.8%</td>
</tr>
</tbody>
</table>

Findings: PartoSure was found to be over 4 times more reliable in predicting sPTD than using fFN detection. With fewer false positives PartoSure maybe be valuable in improved classification of patients requiring intervention, allowing for a potential reduction in unnecessary admissions, avoidable treatments and hospital resources.
Preterm labor and birth management: recommendations from the European Association of Perinatal Medicine (3)


**Objective:** The European Association of Perinatal Medicine (EAPM) developed these guidelines based on recent evidence as adapted to a European perspective of the challenge of PTL and birth management.

**Findings:** In symptomatic women, biomarker measurement in cervicovaginal secretions is one proposed method of increasing the accuracy of cervical length (CL) measurement alone. Publications have observed that when used in combination, the diagnosis of PTL and prediction of spontaneous preterm delivery is improved.

In asymptomatic women, when the CL is between 15-30 mm, CL has the lowest predictive value. In these cases, the EAPM recommends combining the measurement with the biomarker test exhibiting the highest NPV and PPV which can be given shortly after a vaginal examination. In Europe, according to published data, this would be PartoSure.
Clinical symptoms alone are not enough to predict imminent spontaneous delivery in symptomatic women

The combined value of PAMG-1 detection and cervical length via transvaginal ultrasound in the diagnosis of preterm labor in symptomatic patients (4)


Objective: Prospective trial to assess the performance of PartoSure in combination with CL measurement via transvaginal ultrasound for prediction of delivery within 7 and 14 days of testing patients presenting with symptoms of PTL.

Study population: N: 99, GA: 22-36½ weeks

PartoSure Results:
≤ 7 Days: PPV: 75% | NPV: 100%
≤ 14 Days: PPV: 88% | NPV: 100%

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Comparison of the effectiveness of a PAMG-1 test and standard clinical assessment in the prediction of preterm birth and reduction of unnecessary hospital admissions (5)


Objective: Prospective trial to assess the performance of PartoSure vs standard clinical assessment (SCA) for the risk assessment of sPTD within 7 and 14 days of testing patients who present with symptoms of PTL.

Study population: N: 132, GA: 24-36½ weeks

PartoSure Results:
≤ 7 Days: PPV: 75% | NPV: 97.9%
≤ 14 Days: PPV: 87.5% | NPV: 95.7%

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PartoSure Results:
≤ 7 Days: PPV: 75% | NPV: 97.9%
≤ 14 Days: PPV: 87.5% | NPV: 95.7%

Findings: When used in combination with CL of 15-30 mm, PartoSure is highly predictive of imminent sPTD in women presenting with threatened PTL. As a combined assessment, PartoSure and CL was a more accurate identification of those at high risk of delivery, reducing unnecessary admissions and treatments.

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Published data on digital examination and PartoSure

**Objective:** Prospective, observational study to assess if PartoSure could be used after vaginal examinations, such as digital examination and cervical length measurement via transvaginal ultrasound.

**Study population:** N: 41, GA: 24-34 weeks

**Findings:** 100% of test results remain negative or positive after digital examination and 95.1% after transvaginal ultrasound. These findings indicate the performance of a digital examination prior to specimen collection does not affect PartoSure test results.

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PartoSure vs detection of fFN

**Objective:** Prospective trial comparing PartoSure to both detection of fFN and cervical length measurement for the prediction of delivery within 7 and 14 days of testing patients presenting with symptoms of PTL. Additionally, the combination of each biomarker test alongside CL measurement was studied.

**Study population:** N: 203 (fFN 66), GA: 20-36.6/7 weeks

**PartoSure Results:**
- ≤ 7 Days: PPV: 76% | NPV: 96%
- ≤ 14 Days: PPV: 81% | NPV: 89%

**Performance of testing methods for sPTD ≤ 7 Days in singleton patients**

<table>
<thead>
<tr>
<th>Testing method</th>
<th>SN</th>
<th>SP</th>
<th>PPV</th>
<th>NPV</th>
</tr>
</thead>
<tbody>
<tr>
<td>PartoSure</td>
<td>80</td>
<td>95</td>
<td>76</td>
<td>96</td>
</tr>
<tr>
<td>QuikCheck fFN</td>
<td>50</td>
<td>72</td>
<td>29</td>
<td>87</td>
</tr>
<tr>
<td>CL (&lt;25 mm)</td>
<td>57</td>
<td>73</td>
<td>30</td>
<td>89</td>
</tr>
</tbody>
</table>

**Prediction of sPTD ≤ 7 days among singleton patients exhibiting symptoms of PTL**

Findings: Study results found that among these three methods PartoSure shows the highest sensitivity, specificity, PPV and NPV. When CL is least accurate (between 15-30 mm), the PPV and NPV were the highest when the combination of PartoSure and CL measurement was utilized.

*The FDA-approved PartoSure product requires collection prior to digital examination.*
Reducing unnecessary interventions may lead to decreased costs

Placental Alpha Microglobulin-1 in combination with transvaginal ultrasound for prediction of preterm birth (8)

Heverhagen et al. (2015) Perinat Med 43 (S1), 240

**Objective:** Prospective trial to assess the performance of PartoSure in combination with cervical length measurement via transvaginal ultrasound for prediction of sPTD.

**Study population:** N: 64, GA: 24-37\(^{6/7}\) weeks

**PartoSure Results:**
≤ 7 Days: PPV: 100% | NPV: 94%

9% of symptomatic patients delivered within 7 days
83% were hospitalized
75% received corticosteroids
59% received tocolytic therapy

**Findings:** When used alongside CL measurement (N: 31) the PartoSure test had a PPV of 100% and NPV of 97%. Additionally, the investigators found a high rate of unnecessary use of corticosteroids, tocolytics and hospitalization. Utilizing a method with a high PPV may reduce costs and improve patient safety and this study proposed one opportunity could be the combined use of CL measurement and PartoSure.

Utilization of a novel biomarker test (PartoSure PAMG-1) to reduce the length of stay in patients with threatened preterm labor and a short cervix (9)


**Objective:** Prospective, observational trial to evaluate PartoSure as a tool to decrease length of hospitalization for patients presenting with a short cervix and signs and symptoms of sPTD. Admission and treatment were done according to local guidelines based on CL ≥ 25 mm.

**Study population:** N: 45, GA: 24-34\(^{6/7}\) weeks

**PartoSure Results:**
≤ 7 Days: PPV: 60% | NPV: 100%

The average length of stay was 8.4 days
53% of the patients were admitted
70% of admitted patients received corticosteroid therapy
100% received tocolytic therapy
8% received antibiotics

None of them delivered within 7 days

**Findings:** A negative PartoSure test in combination with clinical assessment can decrease unnecessary admissions and acute interventions, reduce the length of stay and minimize unnecessary treatment.
## Publication Summary Table

Publication summary for studies that examined the predictive performance of PartoSure for sPTD within 7 days in patients with signs and symptoms of PTL. Studies are further classified based on the prevalence of sPTD within 7 days. Higher risk groups were classified as such due to the lower risk patients being screened out by initial procedural CL measurement.

<table>
<thead>
<tr>
<th>Study</th>
<th>Population</th>
<th>Year</th>
<th>N</th>
<th>Prevalence of sPTD</th>
<th>PPV</th>
<th>NPV</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Low Risk (≤5%)</strong></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Wing et al.(^1)</td>
<td>US</td>
<td>2017</td>
<td>635</td>
<td>2%</td>
<td>23%</td>
<td>99%</td>
</tr>
<tr>
<td>Melchor et al.(^2)</td>
<td>Europe</td>
<td>2017</td>
<td>745</td>
<td>3%</td>
<td>35%</td>
<td>98%</td>
</tr>
<tr>
<td>Ravi et al.(^10)</td>
<td>Middle East</td>
<td>2017</td>
<td>72</td>
<td>4%(^1)</td>
<td>40%</td>
<td>99%</td>
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<tr>
<td><strong>Intermediate Risk (5-15%)</strong></td>
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<tr>
<td>Fatkullin et al.(^9)</td>
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<td>45</td>
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<td>60%</td>
<td>100%</td>
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<tr>
<td>Nikolova et al.(^11)</td>
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<td>328</td>
<td>8%</td>
<td>60%</td>
<td>98%</td>
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<tr>
<td>Lofti et al.(^5)</td>
<td>Middle East</td>
<td>2017</td>
<td>148</td>
<td>9%</td>
<td>75%</td>
<td>98%</td>
</tr>
<tr>
<td>Heverhagen, A.(^8)</td>
<td>Europe</td>
<td>2015</td>
<td>64</td>
<td>9%</td>
<td>100%</td>
<td>94%</td>
</tr>
<tr>
<td>Lou et al.(^13)</td>
<td>Europe</td>
<td>2016</td>
<td>65</td>
<td>9%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Konoplyannikov et al.(^13)</td>
<td>Europe</td>
<td>2016</td>
<td>71</td>
<td>11%</td>
<td>55%</td>
<td>97%</td>
</tr>
<tr>
<td>Hadzi-Lega et al.(^14)</td>
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<td>2017</td>
<td>57</td>
<td>11%</td>
<td>50%</td>
<td>98%</td>
</tr>
<tr>
<td>Bolotskikh et al.(^4)</td>
<td>Europe</td>
<td>2017</td>
<td>99</td>
<td>12%</td>
<td>75%</td>
<td>100%</td>
</tr>
<tr>
<td><strong>High Risk (≥15%)</strong></td>
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</tr>
<tr>
<td>Nikolova et al.(^7)</td>
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<td>2015</td>
<td>203</td>
<td>17%</td>
<td>76%</td>
<td>96%</td>
</tr>
<tr>
<td>Nikolova et al.(^15)</td>
<td>Europe</td>
<td>2014</td>
<td>101</td>
<td>20%</td>
<td>78%</td>
<td>97%</td>
</tr>
</tbody>
</table>

*PartoSure test taken alongside CL measurement*
The PartoSure Test is intended for in vitro diagnostic use.

References:


This global summary of literature describes the results of various studies and is not intended to represent approved claims.

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