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| **E.1 - The prognosis of GERD in infants and children** | | | | | | | | |
|  |  |  |  | Esophagitis at baseline | | | | No esophagitis at baseline |
| *Microscopic* | *Macroscopic* | | *Macroscopic* |  |
|  | **Outcome** | **In analysis** | **Follow-up time** | Orenstein et al. (n=19) | | Shepherd et al.  (n=126)# | El-Serag et al.  (n=207) | Ruigomez et al.  (n=1242) |
|  | Infants only  (1.5-8.0 months) | | Infants and children  (2.5 months-10 years) | Children only  (1-17 years) | |
| **Clinical signs and symptoms** | | | | | | | | |
| - General | Persisting symptoms OR on GERD treatment at end of follow-up | 34/126 (27.0%)# | 18 months |  | | 21/34  (62%; p=NA) |  |  |
| 80/207 (38.6%) | > 5 years after initial diagnosis |  | |  | 55/80  (68.8%; p=NA) |  |
| 16/19  (84.2%) | 12 months | 6/16  (37.5%; p=NA) | |  |  |  |
| - I-GERQ-R | > 7 | 10/19\*  (52.6%) | 12 months | 0/10  (0%; p=0.001) | |  |  |  |
| - Crying | > 1 hour of the day | 1/10  (10.0%; p=0.007) | |  |  |  |
| - Regurgitation | > 3 times per day | 0/10  (0%; p=0.01) | |  |  |  |
| Monthly in past year | 80/207 (38.6%) | >5 years after initial diagnosis |  | |  | 45/80  (56.3%; p=NA) |  |
| Weekly in past year |  | |  | 5/80  (6.3%; p=NA) |  |
| - Heartburn | Monthly in past year |  | |  | 64/80  (80.0%; p=NA) |  |
| Weekly in past year |  | |  | 16/80  (20.0%; p=NA) |  |
| **Endoscopic complications** | | | | | | | | |
| - Esophagitis | Macroscopic | 14/207 (6.8%) | >5 years after initial diagnosis |  | |  | 3/14  (21.4%;p=NA) |  |
| Microscopic | 10/19 (52.6%) | 12 months | 10/10  (100%; p=NA) | |  |  |  |
| Not specified | 1242/1242 (100%) | 4 ± 1.9 years |  | |  |  | 18/1242  (1.4%;p=NA) |
| - Barret’s esophagus | Intestinal metaplasia in columnar-lined esophagus | 14/207 (6.8%) | >5 years after initial diagnosis |  | |  | 0/14  (0% p=NA) |  |
| Not specified | 1242/1242 (100%) | 4 ± 1.9 years |  | |  |  | 0/1242  (0%;p=NA) |
| NA=not available; I-GERQ-R = Infant Gastroesophageal Reflux Questionnaire Revised. #Data only provided for those patients with proven esophagitis (macroscopically) at baseline (n=34). \*Analysis included only those patients (n=10) that did not require rescue medication and were not withdrawn from the study during the 12 months of follow-up. | | | | | | | | |

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| **F.2 - What are prognostic factors in infants and children with GERD?** | | | | |
| **Prognostic factor** | **Outcome** | **Determinant** | **Results; n, %** | **p-value** |
| **Clinical signs and symptoms (El-Serag et al.)** | | | | |
| **Gender** | Weekly heartburn or regurgitation | Male  Female | 6/32 (19%)  12/48 (25%) | 0.51 |
| **Age of onset GERD** |  | ≤ 5 years  > 5 years | 17/54 (31%)  1/26 (4%) | **0.03** |
| **Ethnic group** |  | Caucasian  Non-Caucasian | 13/58 (22%)  4/22 (18%) | 0.98 |
| **Family history** |  | Yes  No | 7/29 (24%)  11/51 (22%) | 0.79 |
| **Endoscopic complications (Ruigomez et al.)** | | | | |
| **Gender** | Esophagitis (not specified) | Male  Female | 52/632 (19%)  47/629 (7.6%) | > 0.10 (\*p = 0.62) |
| **Age of onset GERD** |  | ≤ 5 years  5 – 11 years  12 – 17 years | 27/261 (10.3%)  26/310 (8.4%)  46/671 (6.9%) | > 0.10 (\*p = 0.20) |
| **Visits to PCP** |  | 1 – 3  4 – 10  > 10 | 32/434 (7.4%)  44/552 (8.0%)  23/256 (9.0% | > 0.01 (\*p = 0.66) |
| **Initial diagnosis** |  | Heartburn  GERD | 17/458 (3.7%)  82/784 (10.5%) | **< 0.005** |
| **Acid suppressants at time of diagnosis** |  | No  Antacids only  H2RA +/- antacids  PPI +/- antacids  H2RA + PPI +/- antacids | 17/261 (6.5%)  23/480 (4.8%)  20/245 (8.2%)  32/220 (14.5%)  7/36 (21.2%) | **< 0.005** |

GERD = gastroesophageal reflux disease; PCP = primary care physician; H2RA = Histamine Receptor Antagonist; PPI = proton pump inhibitor

\*p: Indicates p-value calculated manually by using *Χ2 - test* based upon original data (no level of significance specified in original study).