

4.0 METHODOLOGY

4.1 Study Design

Retrospective Study

4.2 Duration and Location

The study was conducted from 1st June 2007 to 31st August 2008 at the Clinical Oncology Unit, University Malaya Medical Centre.

4.3 Study Population

All women diagnosed with non-metastatic invasive breast cancer in University Malaya Medical Centre between 1st January 1999 and 31st December 2000 were identified.

Patients who defaulted surgery and adjuvant treatment were excluded from the study analysis.

4.4 Data Collection

Case notes were traced from the record office at Clinical Oncology Unit and the UMMC medical records department. The case notes were studied to obtain the patient demographics, clinicopathological details, treatment and relapse information. Survival data was obtained from the National Registry of Birth and Death in March 2006. Patients who were lost to follow-up were contacted to determine their current status. Those who were not contactable were censored

as status unknown. The data was transferred to the Breast Cancer Study Proforma as outlined in Appendix 1. Subsequently, the data was entered into the SPSS program for analysis.

Staging of the cancer was based on the TNM Classification of Malignant-Tumours 2002 by the American Joint Committee on Cancer.

Sites of relapse were categorised into local, regional and distant. Local relapse was defined as relapsed disease in the conserved breast or the chest wall if patient had undergone mastectomy. Regional relapse was defined as further disease in the regional lymph nodes which included ipsilateral axillary nodes, supraclavicular and infraclavicular fossa. Distant or systemic relapse was defined as distant sites of disease relapse. Relapses were recorded according to the first or most significant site of relapse. Patients who relapsed with local and distant disease simultaneously would be recorded as distant relapse.

Disease free interval was defined as the time from the date of primary breast cancer excision to the date of relapse. Overall survival was defined as the time from the date of relapse to the date of terminal event defined as death due to any cause. Analysis of the overall survival for different sites of distant relapse was carried out on patients with only one site of distant relapse.

4.5 Statistical Analysis

Statistical analysis was performed using SPSS version 16.0 software. Univariate and multivariate analyses were used to analyse demographics and clinicopathological factors. Overall survival was analysed using the Kaplan and Meier method and compared by the log rank test.